

EXHIBIT 456

Global Vaccine Market Features and Trends



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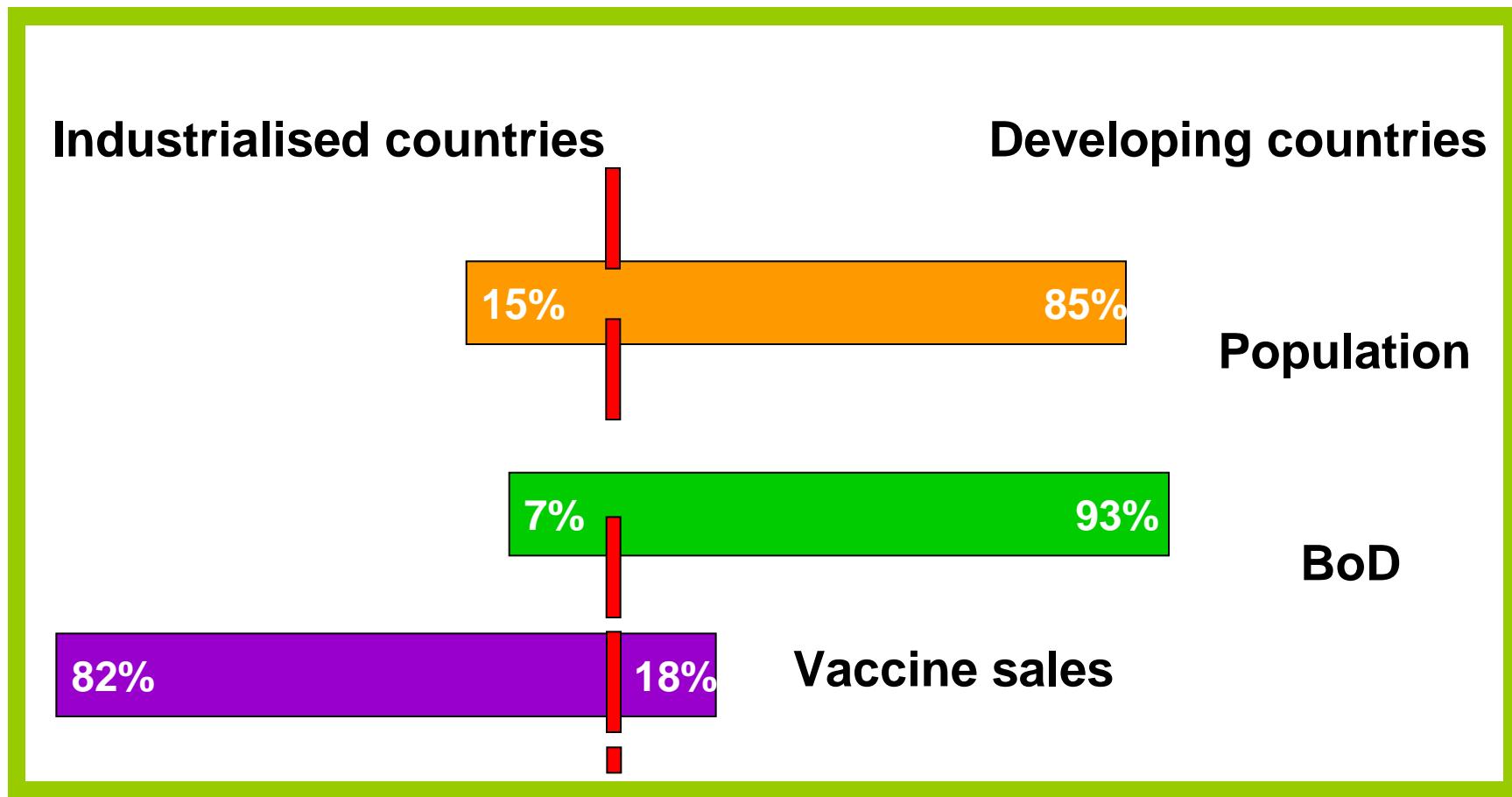
GLOBAL VACCINE MARKET

- MAIN FEATURES OF THE VACCINE MARKET ?
- NEW TRENDS SINCE 2000 ?
- IMPLICATIONS ?



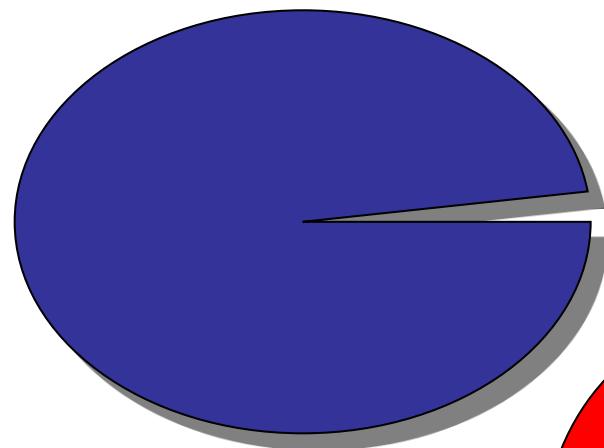
Vaccine Market

North – South GAP

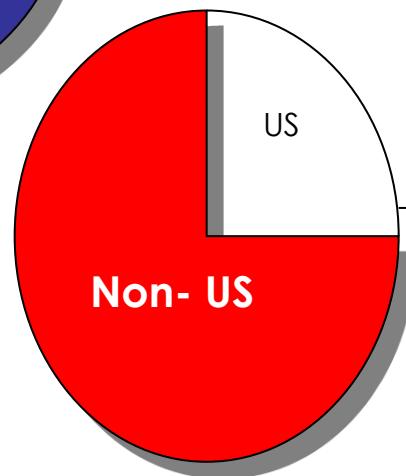


VACCINE MARKET STRUCTURE 2010

World sales for drugs



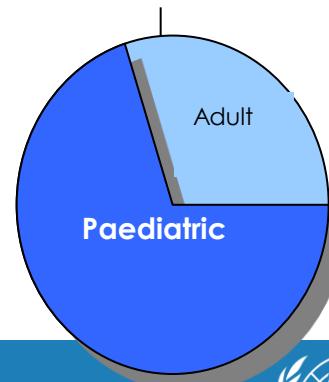
Vaccines



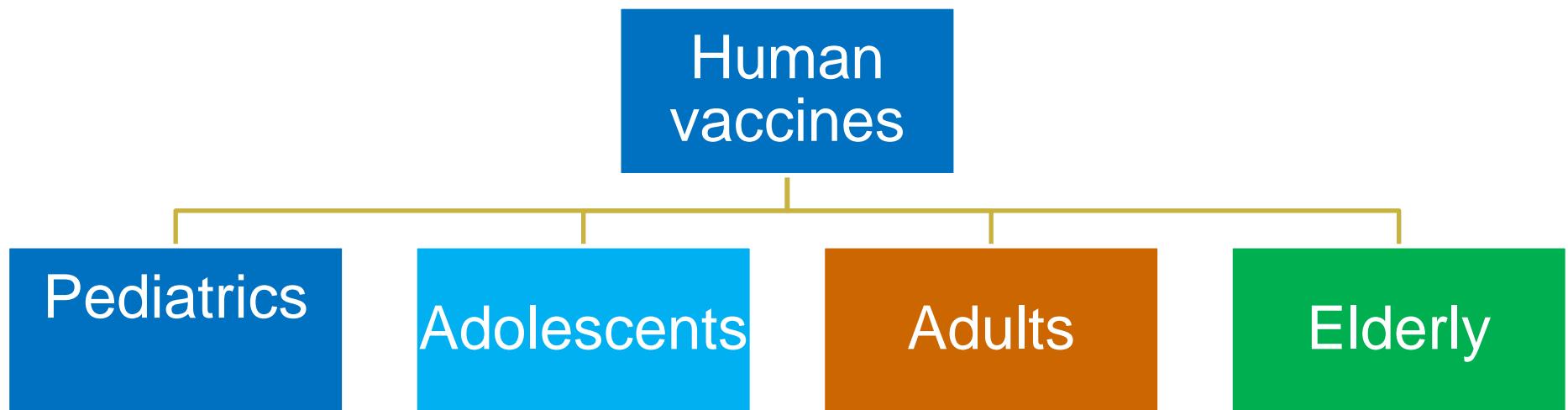
Small size market : 2/3% of the global pharmaceutical market but ...

Spectacular growth rate : 10 - 15% per year versus 5-7 % for Pharmaceuticals

US share



Vaccine segments



GLOBAL VACCINE MARKET: RAPID GROWTH and CHANGING STATUS

- Tripled in value from USD 5B in 2000 to almost USD 24 B in 2013
 - Influenza vaccine market: estimated at \$2.9 billion in 2011 to \$3.8 billion by 2018
 - US : \$1.6 billion in 2011 to \$2.2 billion in 2018
- Global market projected to rise to USD 100 B by 2025
- More than 120 new products in the development pipeline
- 60 are of importance for developing countries
- Vaccines: becoming an engine for the pharmaceutical industry
- Changing status of the vaccines within the pharmaceutical industry
- New business model for vaccines is emerging?

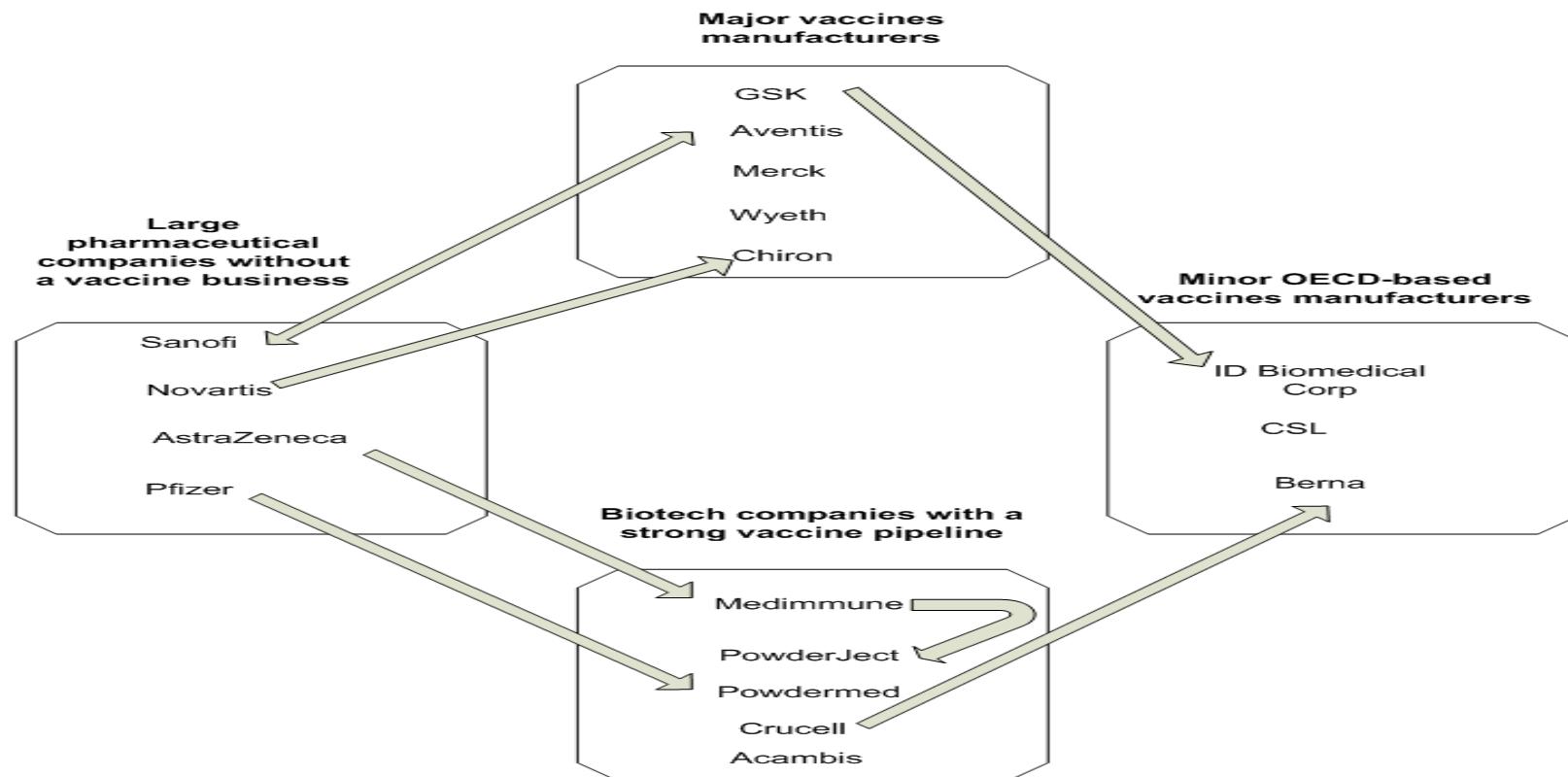
Main features of Vaccine market (2)

- Newer and more expensive vaccines are coming into the market faster than ever before
- Growing concentration in OECD countries but also newcomers (Pfizer, J&J,...)
- Vaccine development: increasing investment



MERGERS AND ACQUISITIONS 2002-2007: Illustration

Mergers and acquisitions in the vaccine industry, 2002-2007



Note. Double arrows denote mergers, single arrows denote acquisitions where the origin of the arrow is the buyer. Headings (such 'large pharmaceutical companies without a vaccine business') and company names refer to the situation in 2002.

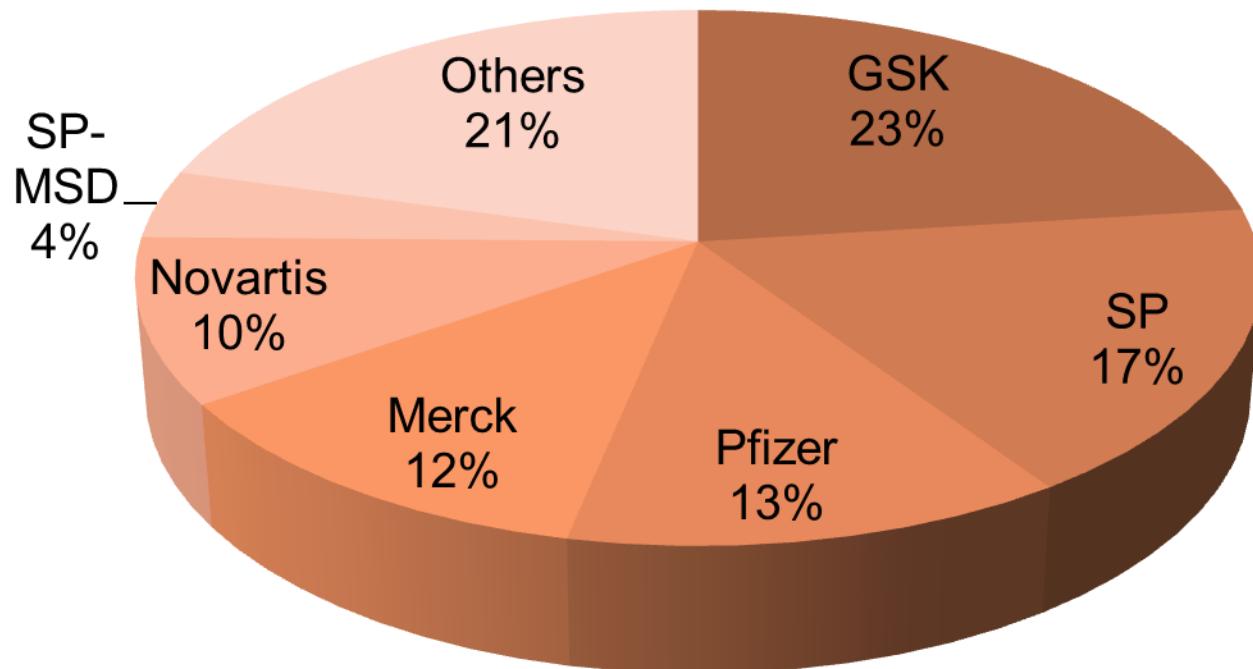


Overview of major vaccine related acquisitions (2005-2012)

Target Company	Acquiring Company	Investment Made	Date Announced
1.Bilthoven Bio of Netherlands	Serum Institute of India Ltd	Euros 80M	July 2012
2.Zhejiang Tianyuan Bio	Novartis	\$ 125 M?	March 2011
3.Wyeth	Pfizer	\$68 bn	Jan 2009
4.MedImmune	AstraZeneca	\$15.6 bn	April 2007
5.Chiron	Novartis	\$5.1 bn	Oct 2005
6.Crucell	Johnson & Johnson	\$2.6 bn	Sep 2009
7. ID Biomedical	GSK	\$1.4 bn	Sep 2005
8.Shantha Bio	Sanofi Aventis	\$781 mn	July 2009
9.Acambis	Sanofi Aventis	\$549 mn	July 2008
10. Intercell	Novartis	\$363 mn	July 2007
11. Corixa	GSK	\$300 mn	May 2005
12. PowderMed	Pfizer	\$230 mn	Oct 2006
13. Coley	Pfizer	\$214 mn	Nov 2007

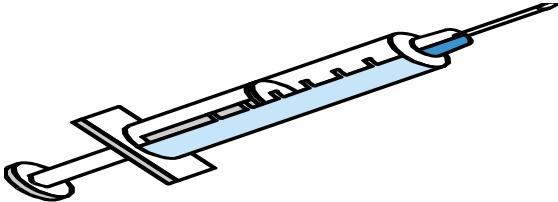
Source: VacZine Analytics + Fierce vaccine

Global vaccine leaders



- 5 large multi-national corporations make up 80% of the global market
- Major focus on new vaccine development for industrialised country markets





Top product sales in 2010

Brand name (producer)	Type/composition	2010 sales (US\$)
Prevnar-13 (Pfizer)	13-valent pneumococcal conjugate vaccine	\$2.4 billion
Proquad (Merck/Sanofi-Aventis)	Measles-mumps-rubella and varicella combination vaccine (MMR-V)	\$1.4 billion
Gardasil (Merck)	HPV	\$1.35 billion
Prevnar (Pfizer)	7-valent pneumococcal conjugate vaccine	\$1.2 billion
Fluzone (Sanofi Pasteur)	Influenza (seasonal and H1N1 strains)	\$1.2 billion
Infanrix and Pediarix) (GSK)	Infanrix = DTaP Pediarix = DTaP-HepB-IPV (combination DPT-based vaccines with acellular pertussis)	\$1.2 billion

Source: Krishan Maggon knoll (<http://knol.google.com/k/krishan-maggon/global-vaccine-market-2010/3fy5eowy8suq3/152...>)





Total sales First half 2012

	Vaccine	Company	H1 Sales	Use
1	Prevnar 13	Pfizer	\$1.847 billion	Pneumococcal infection
2	PENTAct-HIB	Sanofi	\$672 million	Diphtheria, Pertussis/whooping cough; Tetanus; Polio; Haemophilus influenza type b
3	Gardasil	Merck & Co	\$608 million	human papillomavirus (HPV)
4	Pediarix	GlaxoSmithKline	\$535 million	Diphtheria; Tetanus; Pertussis/whooping cough; Hepatitis B; Polio
5	Hepatitis Vaccine Franchise	GlaxoSmithKline	\$500 million	Hepatitis A; Hepatitis B
6	Celtura	Novartis	\$441 million	Swine flu
7	Varivax	Merck & Co.	\$392 million	Varicella virus
8	Cervarix	GlaxoSmithKline	\$285 million	HPV
9	RotaTeq	Merck & Co.	\$284 million	Rotaviral gastroenteritis
10	Synflorix	GlaxoSmithKline	\$274 million	Pneumococcal infection; Otitis media
11	Rotarix	GlaxoSmithKline	\$266 million	Rotaviral gastroenteritis



Total sales First half 2012 (2)



	Vaccine	Company	H1 Sales	Use
12	Zostavax	Merck & Co.	\$224 million	Shingles; Herpes
13	Prevnar 7	Pfizer	\$222 million	Pneumococcal infection; Otitis media
14	Fluzone/Vaxigrip	Sanofi	\$219 million	Influenza
15	Menactra	Sanofi	\$217 million	Meningitis
16	Pneumovax	Merck & Co.	\$213 million	Pneumococcal infection
17	Adacel	Sanofi	\$207 million	Diphtheria; Pertussis/whooping cough; Tetanus
18	MMR-II	Merck & Co.	\$180 million	Measles, Mumps, Rubella
19	Boostrix	GlaxoSmithKline	\$165 million	Diphtheria; Tetanus; Pertussis/whooping cough
20	Biothrax	Emergent BioSolutions	\$88 million	Anthrax

Sources: EvaluatePharma; Fiercevaccines, Sep 2012



VACCINE MARKET : GROWTH FACTORS ?

Combination of :

- Importance of communicable diseases and new threats
- Cost effectiveness of immunizations
- New funding opportunities (Gov, PPP, donors, Foundations,...)
- New research techniques and manufacturing technologies
- Increasing demand, new target population, larger emerging markets
- Higher prices, improved profitability for the industry (blockbuster vaccines..)



Developing countries: vaccine market share and trends

Developing country market

80 % of population / less than 20% of global market

Regular and rapid growth in volume and dollar value

Emerging
economies and
markets

UN market

Private sector in
Low and Middle
income countries

MNC : Key strategies for developing countries

3 main targets:

- Emerging economies
- UN markets (UNICEF/GAVI and PAHO)
- Private sector, middle income group markets

3 main strategies

- Partnerships with emerging economies and manufacturers
- Accelerated uptake and Differential pricing
- Field presence and active marketing, different presentations



Arrangements with emerging economies and manufacturers

- Various types of arrangements, contracts and partnerships
- Taking into account country potentials and particularities:
 - size of population and potential market,
 - legislation favouring or not domestic production and TT,
 - production costs, scientific and technical capacity, price regulation,
 - NIP, immunization in the private sector,
 - regional influence,..
- Directly with countries and local manufacturers or through PPP or PDP

Various types of arrangements

Objectives:

lower costs, increase production capacity, competitive position
access to large public and private market, ...



A new trend: more active vaccine marketing in DC

- Emerging markets such as Mexico, Brazil, Turkey, Indonesia, Russia, China and India are among key priorities for MNC
- Singapour, Malaysia, Vietnam, Philippines, Egypt, GCC and others: second line
- Wide licensing and registration of new and innovative vaccines
- Increased presence of sale forces and MNC representatives : "pharma like model"

New business MNC model is emerging?

- More mapping, market segmentation and price differentiation
- Outsourcing selected part of R&D, production and commercialization/Access to promising markets and local capacities, low costs
- Risk sharing with countries and funders
- Collaborative networks and active presence at GHIs

UN Market: UNICEF and PAHO



Spectacular increase in the last 10 years



Both UNICEF SD and PAHO



Polio, measles, new vaccines



National, regional and global priority



MDGs, GIVS, GAVI, AMC, IFFIm, GPEI,
Measles partnership, BMGF, DOV/GVAP

UN MARKET (in value)

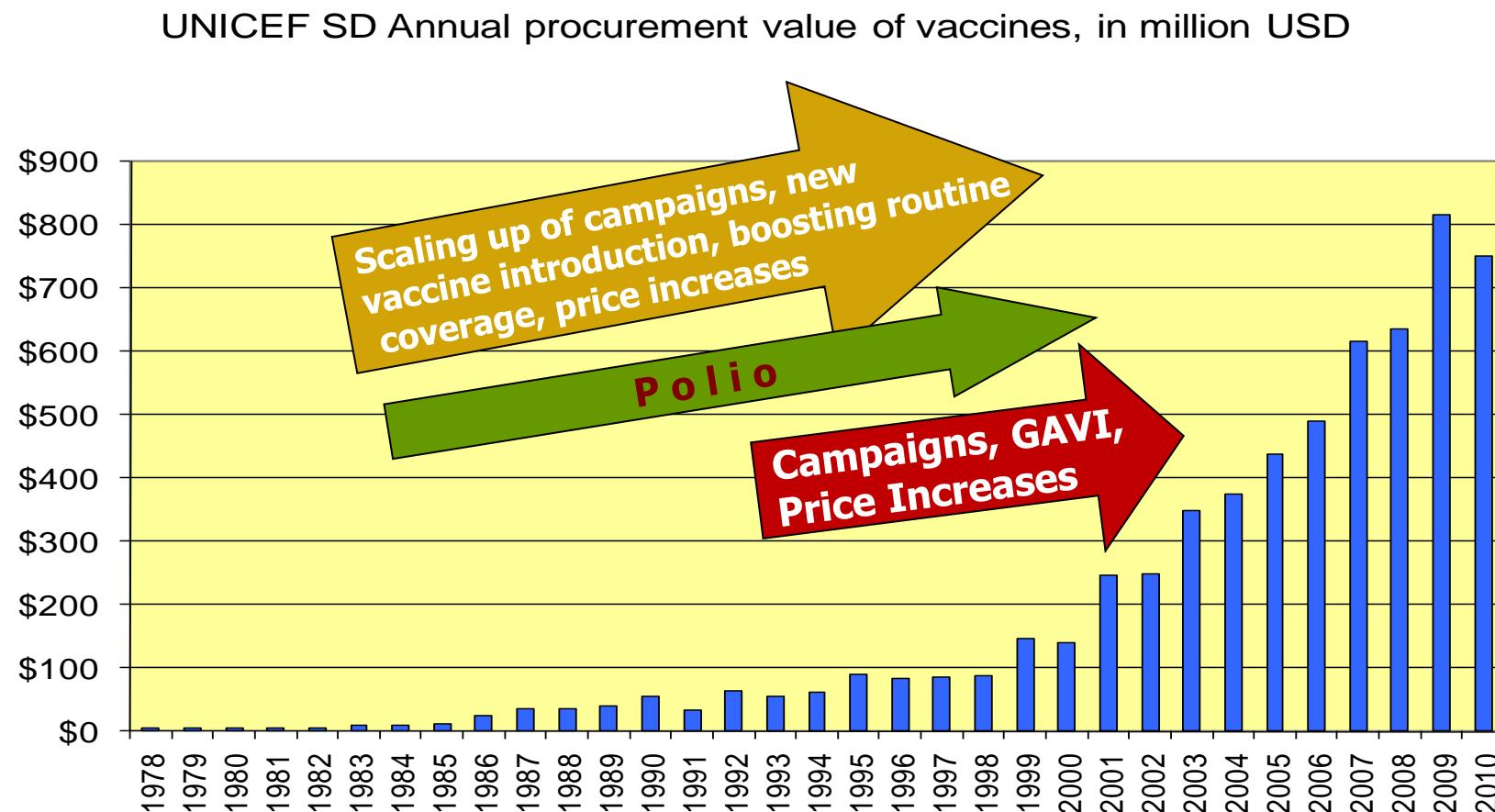
	2002	2011	%
UNICEF SD	\$ 220 million	\$ 1,03 Billion	+ 468%
PAHO RF	\$ 120 million	\$ 400 million	+ 333%
Total	\$ 340 million	\$1,430 billion	+ 420%



Around 7, 5 % of total vaccine sales



UNICEF annual **vaccine procurement** has increased five fold since 2000 - supporting UNICEF Programmes and on behalf of Partners, Global Programmes, Governments and NGO's



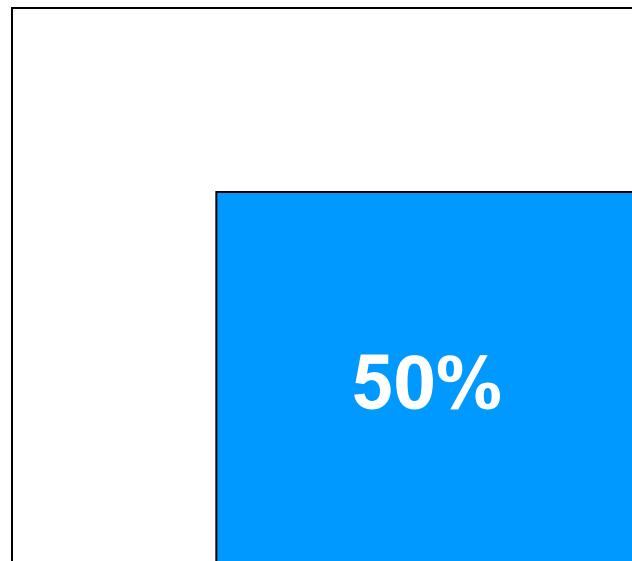
The arrows indicate the main programme drivers for the increased procurement value.

Source UNICEF Supply Division

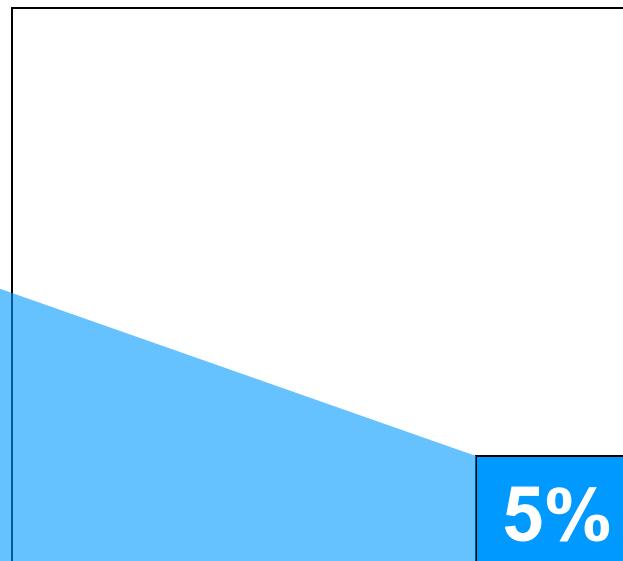


The UNICEF 2012: buying 50% of the global volume of vaccine doses, mainly EPI vaccines, but representing only 5% of total market value

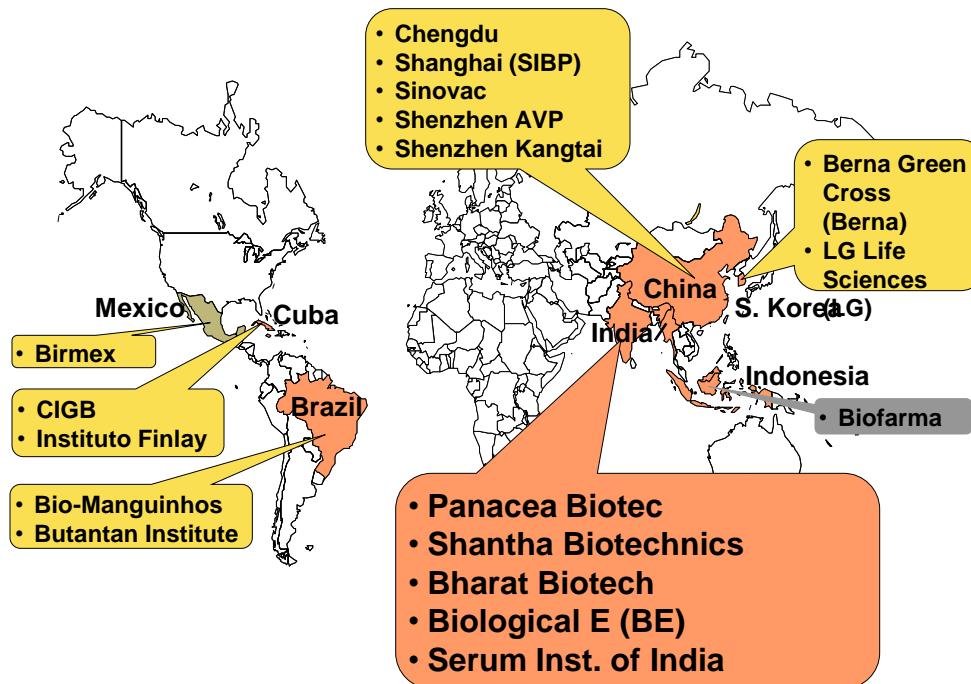
Global Volume of Doses



Global Value of Doses

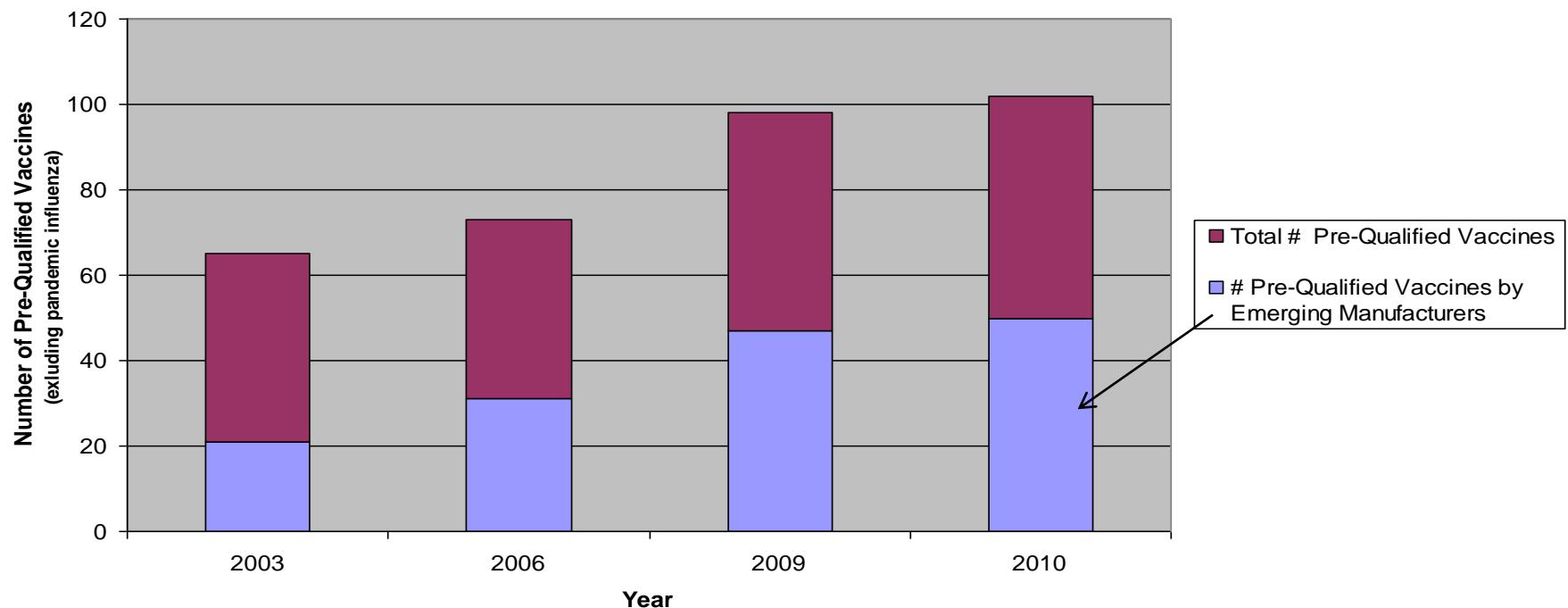


EMERGING MANUFACTURERS ARE PLAYING AN ACTIVE ROLE



Year	Total # Pre-Qualified Vaccines (excluding pandemic influenza)	# Pre-Qualified Vaccines by Emerging Manufacturers (excluding pandemic influenza)	% of Pre-Qualified Vaccines by Emerging Manufacturers	# Emerging Manufacturer Countries with Functional NRA's
2003	66	21	32.3%	6
2006	73	31	42.5%	6
2009	98	47	48.0%	6
2010	102	50	49.0%	7

Number of Pre-Qualified Vaccines by Year with Shares from Emerging Manufacturers



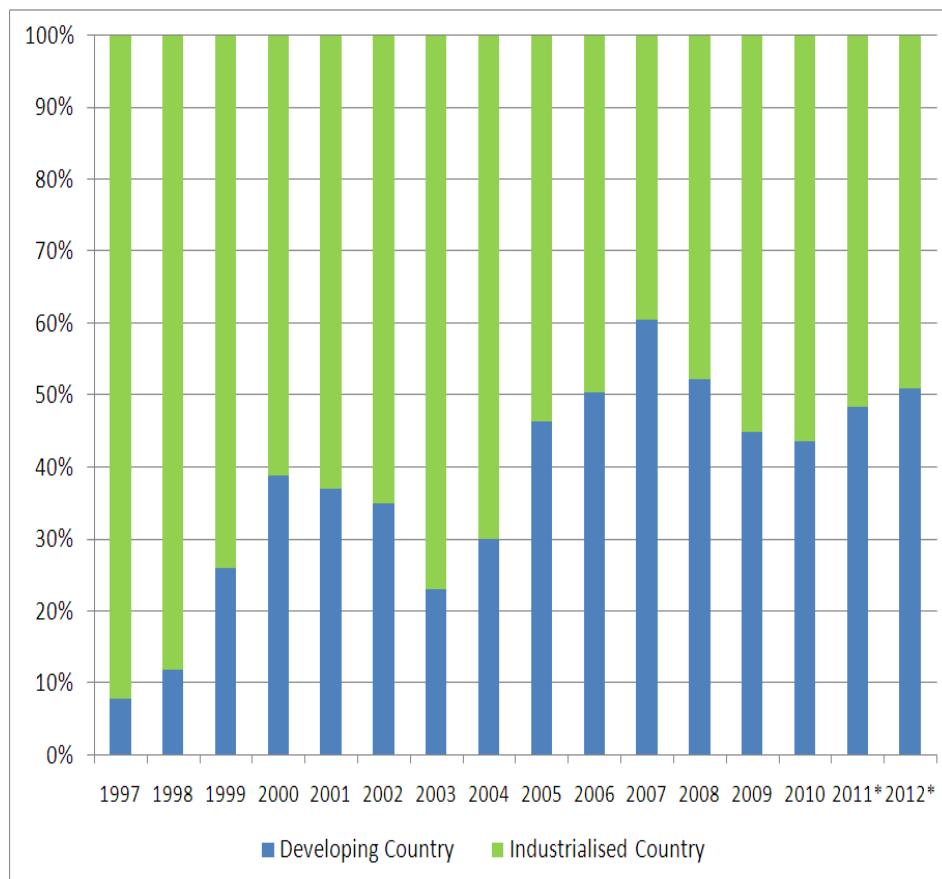
Source: WHO-IVB-QSS. As of September 6, 2010

UNICEF SD

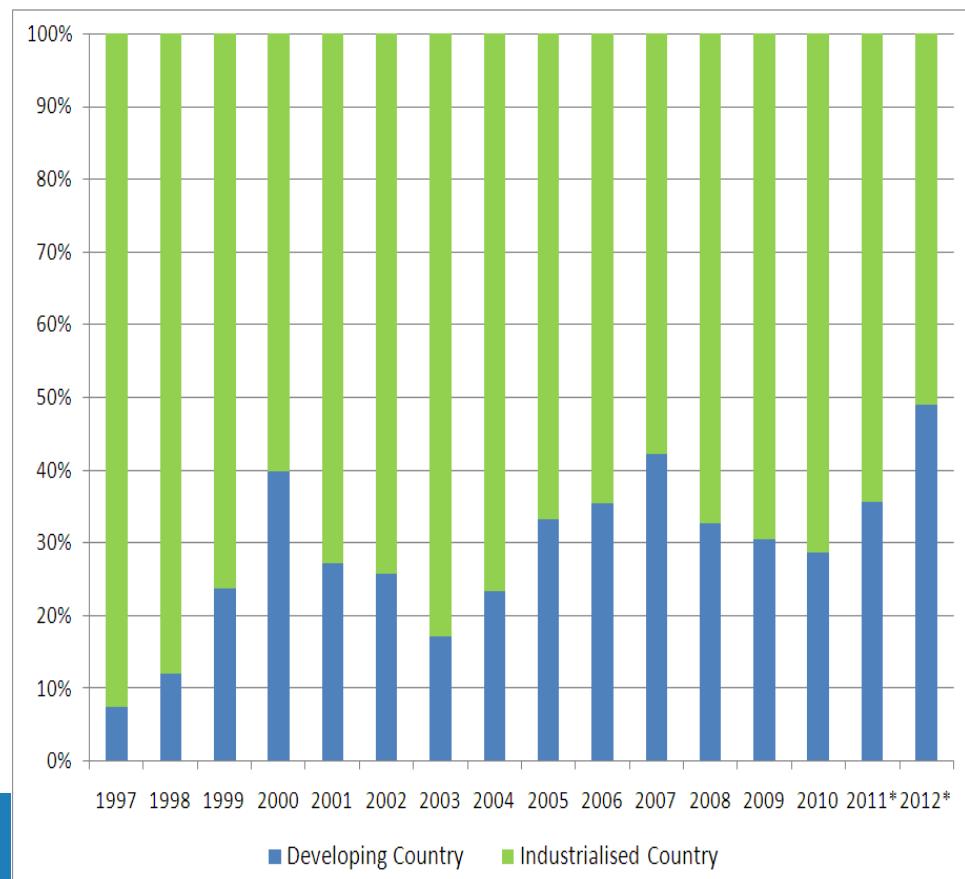
Emerging vs. Industrialized manufacturers

Emerging Market Country Manufacturers make up approximately 50% of procurement volumes in 2010 and 30% by value, predominantly due to lower but increasing participation in new vaccine markets and differing cost bases

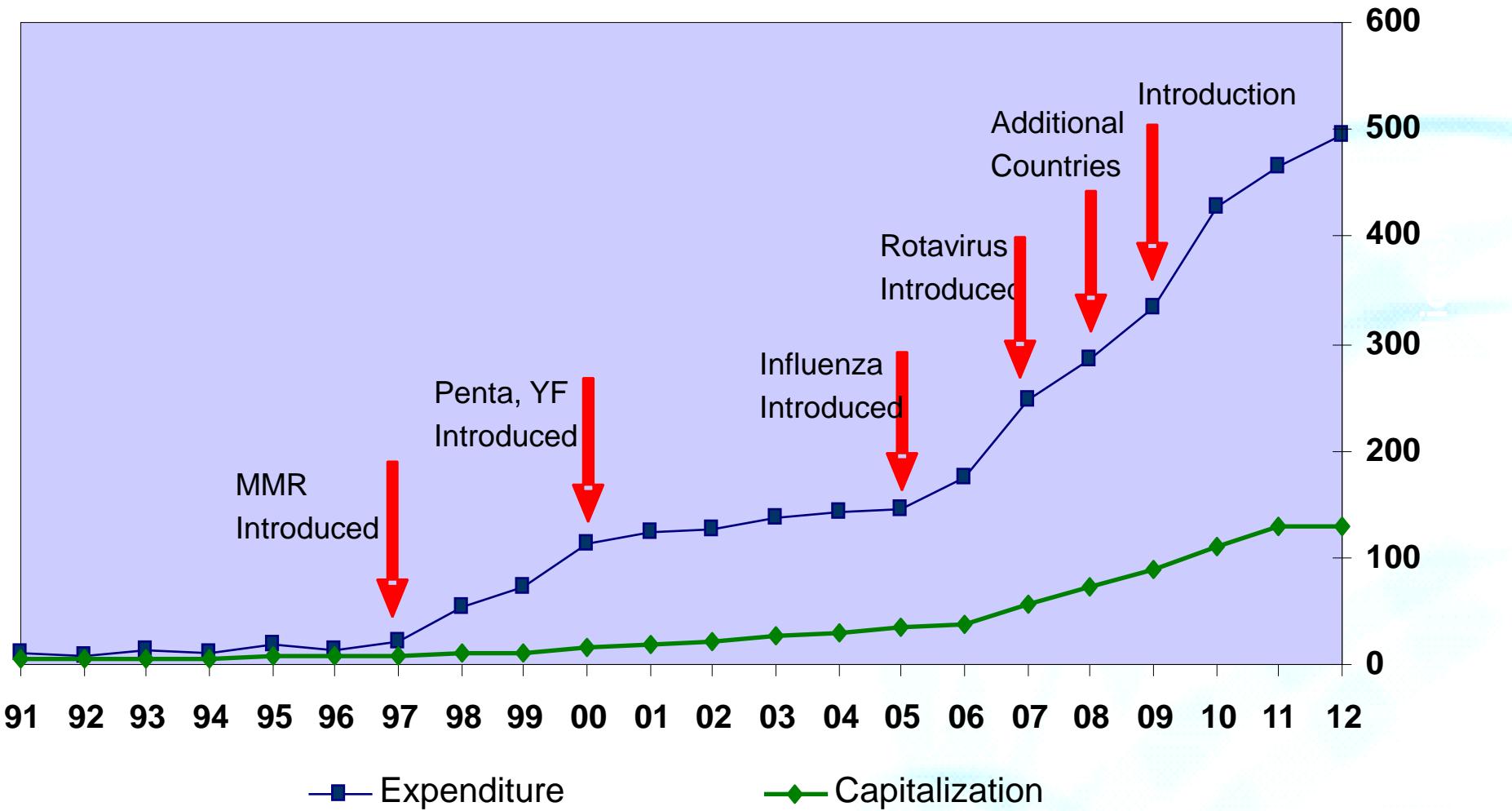
By Volume



By Value



Growth of the PAHO Revolving Fund



Source : WHO PAHO



The PAHO Revolving Fund

Update: 2012



60 products
28 antigens



39 countries & territories



Expected Purchases: US\$ 405 million

Capital Fund: US\$ 100 million

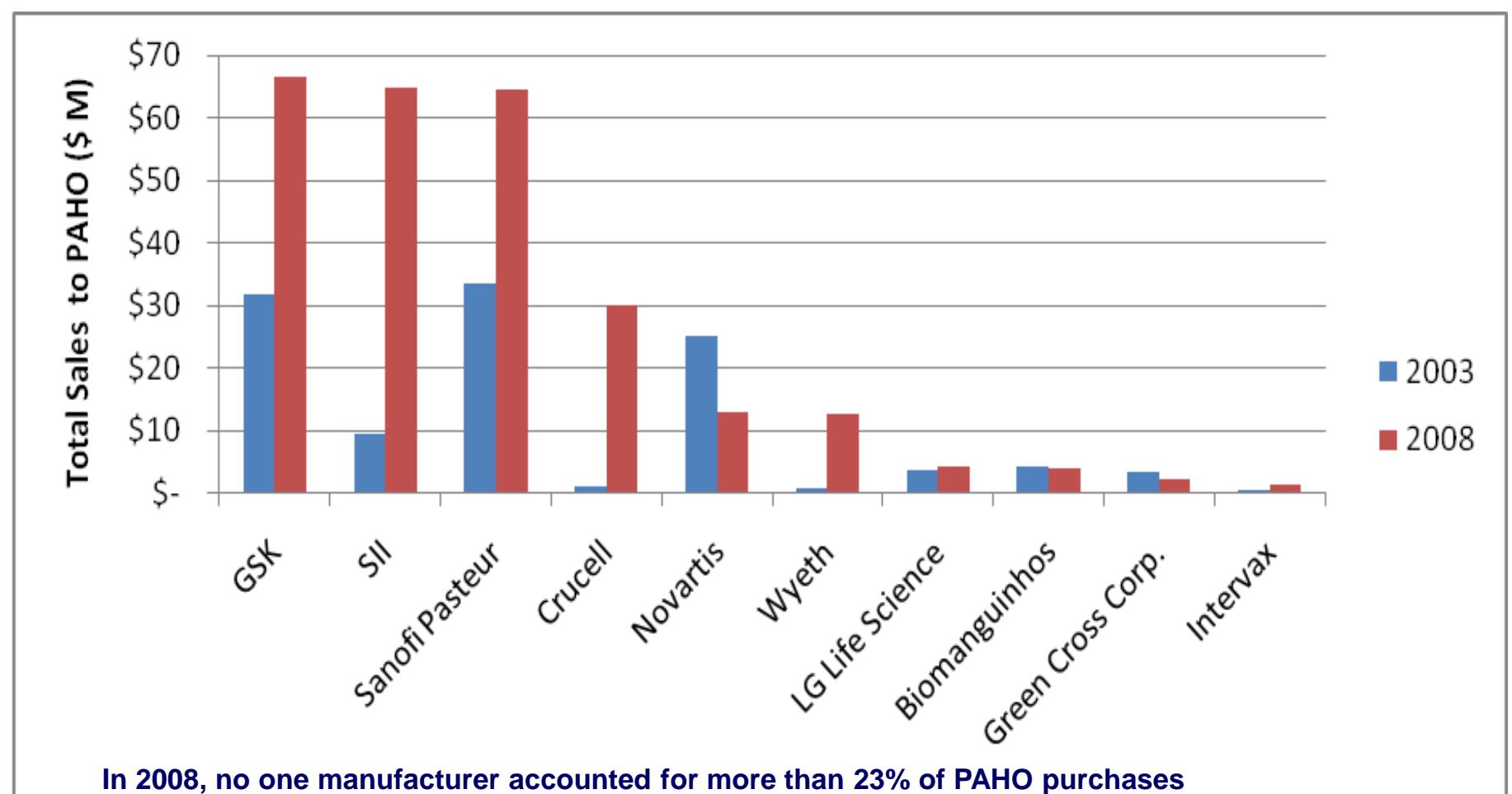
PAHO

30 |



World Health Organization

Top ten suppliers of PAHO RF 2003-2008



NEW TRENDS ?

New trends ?

Demand side

- Vaccines and vaccinations : on the top of GoV and UN agenda, unmet needs
- Accelerate uptake and increasing demand in LIC
- Middle Income countries including emerging Countries

Supply

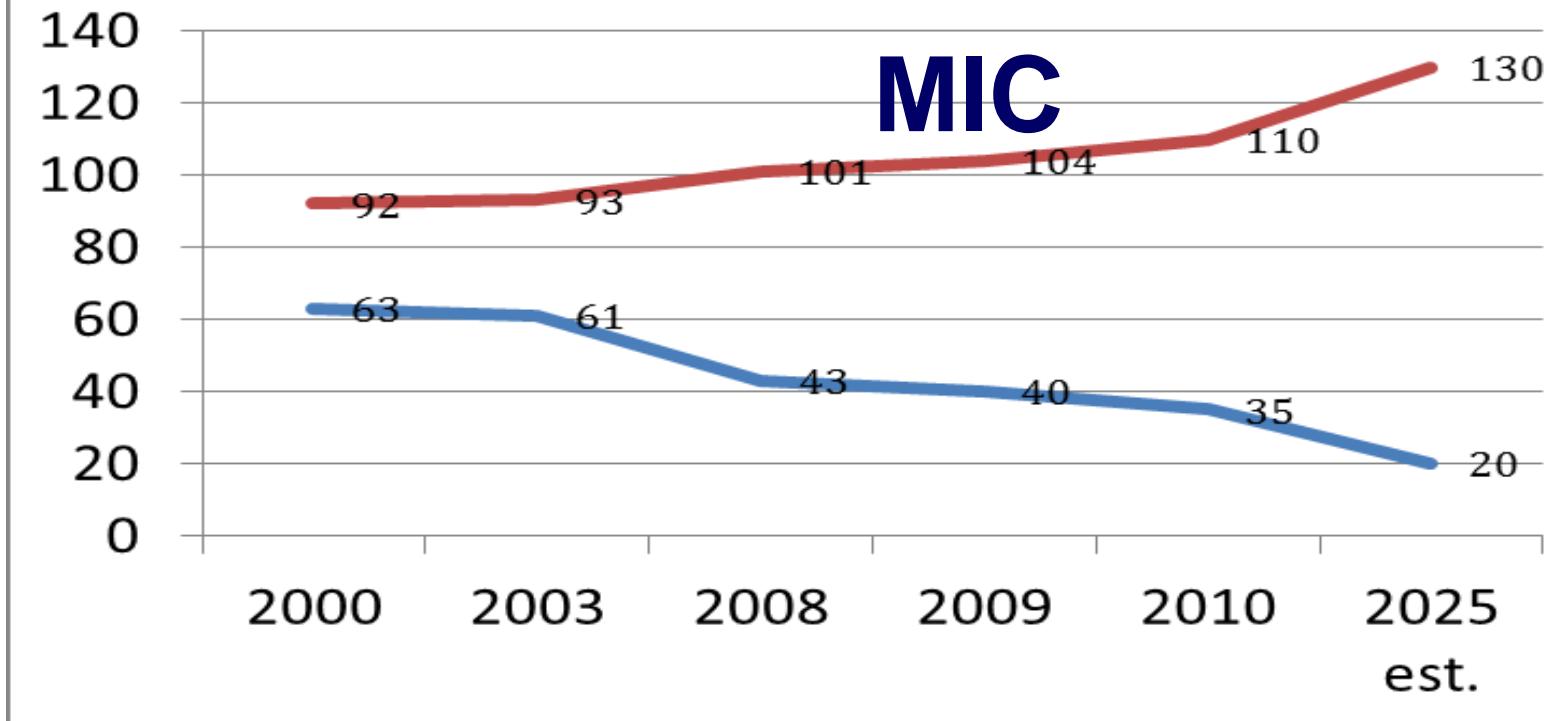
- Increasing capacity
- Remaining tensions on products
- New production and supply strategies

Funding

- GoV resources
- Donors
- Private foundations

More players on demand, supply and financing

By 2025, there will only be 20 LICs



Number of countries by income classification and year

RED = MIC;

BLUE = LIC

Source: Leo and Moss, 2011
CGD A. Glassman

Development of "MIC vaccine market products"

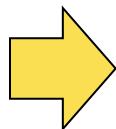
New trends in the last 5 years and their implications

1) Supply side

- Newcomers: Pfizer, Novartis, Johnson and Johnson,...
- New contractual arrangements between MNF/EM/EE
- Outsourcing of production in developing countries
- New commercial and marketing strategies (high volume/lower price, donation, active marketing,...)
- Product/market segmentation and differential pricing
- MNC: new products and presentations with high return,
- EM: basic and underutilized products high volume/low price
- Persistent supply tensions (basic and new vaccines)

Variety of tools to accelerate new vaccine access and to manage risks

- Innovative procurement approaches as pull mechanisms (AMC)
- Push mechanisms to accelerate vaccine supply (such as Men A)
- Long term commitments may be needed to fund vaccines to stimulate capacity expansion (such as YF)



New supply and procurement strategies

- Reduce risks for both producers and purchasers
- Increase predictability and co-responsibilities

Innovative Finance Achieving Results

Tools Used	Transaction Examples	Goal
Volume Guarantee & Prepayment	<p>Rotavirus Vaccine:</p> <ul style="list-style-type: none"> Volume guarantee provided for a portion of the quantities with some volumes paid for in advance Contract duration of 5-years covering 132M doses New vaccine launched and sustained at lower price Financing provided by GAVI, with strategic and technical support from the Gates Foundation ("BMGF") 	<ul style="list-style-type: none"> \$15 per course → €3.76 per course >\$400M in savings over 5 years Prepayment understood to facilitate expected expansion of manufacturing capacity Accelerated introduction of Rotavirus vaccine made possible through certainty provided by commitment in new markets
Volume Guarantee	<p>Oral Polio Vaccine (OPV):</p> <ul style="list-style-type: none"> Firm contract signed for 2011-2012 with large bulk and fill-finish manufacturer who at the time was considering exit of market Duration of 2-years originally covering 270M doses per year (540M doses total) Financing provided by BMGF 	<ul style="list-style-type: none"> Decrease in price offered to <\$0.118 per dose generated significant savings versus current WAP of >\$0.13 Delayed exit of manufacturer by >2 years Increased visibility for manufacturer and certainty of UNICEF procurement during fragile OPV market
Volume Guarantee & Prepayment	<p>Pentavalent Vaccine (lyophilised):</p> <ul style="list-style-type: none"> Contract signed with new entrant to Pentavalent market with volume paid for in advance Duration for <1 year covering 10M doses Financing provided by GAVI 	<ul style="list-style-type: none"> New entrant to market secured volume and able to offer extremely attractive price of \$1.80 per dose, Expanded vaccine security with expanded manufacturing capacity in a fragile market
Volume Guarantee	<p>PCV</p> <ul style="list-style-type: none"> Volume guarantees for 20/10/5% of quantities or years 1/2/3 of 10 year contract Financing provided by GAVI and WB 	<ul style="list-style-type: none"> Part of overall AMC structure to achieve tail price of max. \$3.50 and sufficient production quantities to meet demand

Source: UNICEF SD, DCVMN meeting, Nov 2012



Vaccine Market: Positive trends and Main Issues

- Positive trends
 - Immunizations: on the top of the agenda: DOV ands GVAP
 - Promising vaccine pipeline, R&D
 - Growing support: GAVI partners + Gov funding
 - Multiple initiatives, PDPs and PPPs
 - New players on supply and funding
 - More WHO PQ vaccines leading to competition, price decrease
 - Strategic role of UNICEF SD and PAHO and increasing role of funders
- Concerns :
 - Oligopoly, limited supply for DC and Shortage risks
 - Upstream factors : Technology transfer and IPRs, R&D for most needed vaccines, DCVM R&D capacity , ..
 - New vaccine costs and prices
 - Financial sustainability ? Govt responsibilities role
 - Future of International initiatives
 - Future of Emerging Manufacturers
 - Impact of the financial crisis?



EXHIBIT 457

Summary

GPMB Board Meeting, 1-2 April 2019

IFRC, Geneva, Switzerland

Presentations were made on GPMB commissioned papers exploring country capacity, financing, research and demonstration (R&D), governance and coordination for preparedness, and on a special Independent Oversight Advisory Committee study on lessons learned/lost from past and current Ebola virus outbreaks (EVD) and implications for health emergencies. WHO Director-General Tedros Adhanom Ghebreyesus presented on the status of the current Ebola response in the Democratic Republic of Congo (DRC) and emerging lessons.

Board members acknowledged some encouraging developments over the past three years in improving global preparedness. These include: (a) strengthened emergency preparedness and response capabilities at WHO; (b) greater numbers of countries completing National Action Plan for Health Security (NAPHS) and IHR self-assessment reporting tool (SPAR) and voluntary Joint External Evaluation (JEE) assessments; (c) the establishment and use of emergency financing mechanisms, including the WHO's [Contingency Fund for Emergencies \(CFE\)](#); the World Bank Group's [Pandemic Emergency Financing Facility \(PEF\)](#) and the launch of the [Coalition for Epidemic Preparedness Initiatives \(CEPI\)](#) to develop vaccines for a set of pathogens with pandemic potential; and (d) the development of a platform to fast track vaccine development for Ebola and the deployment/use of an effective experimental Ebola vaccine in the current DRC outbreak, along with other effective treatment approaches.

The Board highlighted several critical issues including:

- *the lack of community trust and acceptance has emerged as a critical bottleneck for effective preparedness and response;*
- *the lack of progress in mobilizing domestic and international financing to prepare and respond to emergencies, and to finance implementation of NAPHS and preparedness in low- and middle-income countries;*
- *the lack of adequate investment in research and development for new tools and technologies needed to mitigate future outbreaks, especially for novel pathogens, particularly medicine and rapid diagnostic countermeasures;*
- *the continuing fragmentation and weak coordination among the various global institutions involved in preparedness; and*
- *the lack of standardized definitions of preparedness (including their use to monitor financing/expenditures)*

The current DRC EVD outbreak highlighted the prominence of very difficult conditions, insecurity, lack of community trust, and the impact of non-health sector contributing factors that hamper effective containment of the outbreak. The Board expressed its thanks to WHO and all partners who have been tirelessly working to control the outbreak under difficult conditions.

Experiences from the DRC EVD outbreak and other health emergencies (e.g., Madagascar and plague) suggest a new world and reality—a “new normal” – characterized by the increasing frequency of and difficulty in managing high impact epidemics and health emergencies occurring in fragile and vulnerable country settings. The precarious situation is aggravated by simultaneous crises, many including prolonged conflict; new types of security issues; lack of trust in institutions; and synergies with other big problems (e.g., urbanization, high population density and movements, ecological and climate changes, complex societies, etc.). This is further compounded by potential existential risks, e.g. a high impact airborne-pathogen pandemic and risks associated with new and mutating viruses.

The Board identified actions and priorities for their attention moving forward, including:

- *placing communities at the centre of preparedness, building trust before any crisis, and empowering community engagement and participation in preventing, preparing for and responding to health crises*
- *global preparation for a fast-moving, high impact airborne pathogen outbreak such as for influenza, or an accidental or deliberate release*
- *improving financing for global preparedness and response, including replenishing the CFE, securing funding for NAPHS, and using innovative financing strategies (e.g., including preparedness in IDA19; & in IMF Article 4 processes)*
- *research and development, notably for developing and rolling out countermeasures for emerging threats,*
- *actively engaging multiple sectors of society, and strengthening governance and coordination*
- *improving measurement approaches for monitoring and accountability, and defining standardized definitions for preparedness*

The GPMB is committed to shine a light on the most critical gaps in global preparedness for outbreaks, pandemics and health crises, and to ensure that robust measurement is in place to combat these threats to our common security. The GPMB will issue its first annual report on the status of global preparedness for health crises, including recommendations and potential solutions in autumn 2019.

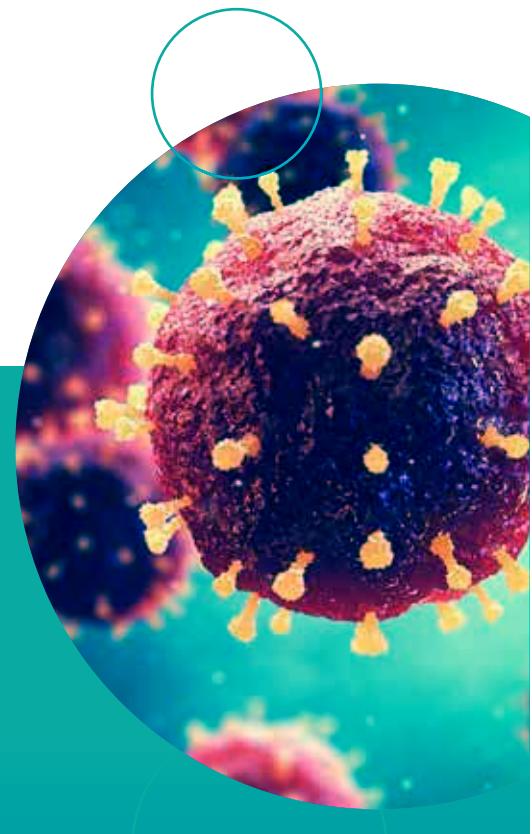
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A WORLD AT RISK

**Annual report on global preparedness
for health emergencies**

Global Preparedness Monitoring Board

September 2019



Acknowledgements

We extend our deepest appreciation to the Director General of the World Health Organization and to the President, World Bank Group for having co-convened the Global Preparedness Monitoring Board (GPMB).

We would like to express our deepest gratitude to the Board members and their staff who gave their time, wisdom and contributions to shaping the report. This report would not have been possible without the many individuals from academic institutions, experts, multilateral agencies, non-governmental organizations and national governments who willingly gave their time, insights, experience and contributions to the Board, to the Secretariat, and especially to the teams developing the background papers for the GPMB.

We extend our warm gratitude to the lead organizations and experts who developed the background papers for the GPMB (please see: www.who.int/gpmb/thematic_report.html for all papers and their contributors; list of organizations in alphabetical order): Anthrologica & the International Federation of Red Cross and Red Crescent Societies; Independent Oversight Advisory Committee (IOAC) for the WHO Health Emergencies Programme; Johns Hopkins University Center for Health Security; University of Oxford & Chatham House; Wellcome Trust; the World Bank Group; and, the World Health Organization.

We express our deep appreciation to the GPMB Secretariat, who, under the direction of Alex Ross, authored the report, with writer Nellie Bristol and significant contributions from Amelie Rioux, Tore Godal and Benedikte Alveberg (co-Chair support teams), from Toomas Palu, Sam Loewenberg, Carolyn Reynolds and Victoria Birungi.

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A WORLD AT RISK

**Annual report on global preparedness
for health emergencies**

Global Preparedness Monitoring Board



About the Global Preparedness Monitoring Board

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As an independent monitoring and advocacy body, the Global Preparedness Monitoring Board (hereafter referred to as the Board or GPMB) urges political action to prepare for and mitigate the effects of global health emergencies. Co-convened in May 2018 by the World Bank Group and the World Health Organization, the Board builds on the work of the Global Health Crises Task Force and Panel, created by the United Nations Secretary-General in the wake of the 2014-2016 Ebola epidemic. The Board works independently of all parties, including its co-conveners, to provide the most frank assessments and recommendations possible. The findings, interpretations, conclusions and opinions expressed in this report and by Board members represent their views only and not those of their organizations or of the co-conveners.

The 15-member Board is made up of political leaders, heads of agencies, and experts, led jointly by Dr Gro Harlem Brundtland, formerly Prime Minister of Norway and Director-General of the World Health Organization and Mr Elhadj As Sy, Secretary General of the International Federation of Red Cross and Red Crescent Societies. Members serve on the Board in their individual capacities.

The goals of the Board are to:

- assess the world's ability to protect itself from health emergencies
- identify critical gaps to preparedness across multiple perspectives;
- advocate for preparedness activities with national and international leaders and decision-makers.

The Board differs from other similar commissions and mechanisms, which are time-limited and often specific to one agency or sector. The Board, with a five-year initial term and benefiting from the engagement of independent experts and the support of a professional Secretariat, will monitor preparedness across a broad range of actors and sectors, urging specific actions to drive change. It complements and enhances existing accountability functions of the World Health Organization, the United Nations, the World Bank and other stakeholders.

Approach to the first annual report – a focus on seven urgent actions

In this first annual report, the Board explores and identifies the most urgent needs and actions required to accelerate preparedness for health emergencies, focusing in particular on biological risks manifesting as epidemics and pandemics. The Board analysed evidence and commissioned seven review papers that explore the challenges of preparedness through various lenses: governance and coordination; country preparedness capacities; research and development; financing; enhancing community engagement and trust; preparing for and managing the fallout of a high-impact respiratory pathogen pandemics; and, lessons learned and persistent gaps revealed by recent outbreaks of Ebola virus disease in Africa. The Board has drawn on these papers and other data to identify areas where preparedness efforts are working and where they are faltering (1).

The Board identified seven actions that leaders must implement to prepare for pressing threats. Some can – and should – be accomplished immediately whereas others are more long-term. One of the Board's first priorities will be to develop a monitoring framework to track progress not only on these actions, but on other national and global political commitments as well. The Board looks forward to engaging with global, regional and national leaders and stakeholders on ways to accelerate progress on these actions.

All background documents, the Board's monitoring framework, strategy, annual plans and related documents are available on the Board's website.

Future GPMB work

Future reports will monitor progress on preparedness for other types of health emergencies, such as those caused by natural disasters. In addition to its monitoring function, the Board will monitor progress in preparedness, assess emerging issues and make additional recommendations as needed.

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**H.E. Dr Gro Harlem
Brundtland**

Co-Chair
Former Prime Minister of
Norway and former WHO
Director-General



Mr Elhadj As Sy

Co-Chair
Secretary-General of the
International Federation of Red
Cross and Red Crescent Societies

While disease has always been part of the human experience, a combination of global trends, including insecurity and extreme weather, has heightened the risk. Disease thrives in disorder and has taken advantage--outbreaks have been on the rise for the past several decades and the spectre of a global health emergency looms large. If it is true to say "what's past is prologue", then there is a very real threat of a rapidly moving, highly lethal pandemic of a respiratory pathogen killing 50 to 80 million people and wiping out nearly 5% of the world's economy. A global pandemic on that scale would be catastrophic, creating widespread havoc, instability and insecurity. The world is not prepared.

Outbreaks hit lower-resourced communities much harder given their lack of access to basic health services, clean water and sanitation; this will aggravate the spread of any infectious pathogen. Disease amplifiers, including population growth and resulting strains on the environment, climate change, dense urbanization, exponential increases in international travel and migration, both forced and voluntary, increase the risk for everyone, everywhere.

Leaders at all levels hold the key. It is their responsibility to prioritize preparedness with a whole-of-society approach that ensures all are involved and all are protected.

The world needs to proactively establish the systems and engagement needed to detect and control potential disease outbreaks. These acts of preparedness are a global public good that must meaningfully engage communities, from the local to the international, in preparedness, detection, response and recovery. Investing in health emergency preparedness will improve health outcomes, build community trust and reduce poverty, thereby also contributing to efforts to achieve the United Nations Sustainable Development Goals.

For its first report, the Global Preparedness Monitoring Board (GPMB) reviewed recommendations from previous high-level panels and commissions following the 2009 H1N1 influenza pandemic and the 2014--2016 Ebola outbreak, along with its own commissioned reports and other data. The result is a snapshot of where the world stands in its ability to prevent and contain a global health threat. Many of the recommendations reviewed were poorly implemented, or not implemented at all, and serious gaps persist. **For too long, we have allowed a cycle of panic and neglect when it comes to pandemics: we ramp up efforts when there is a serious threat, then quickly forget about them when the threat subsides. It is well past time to act.**

The GPMB will advocate at the highest levels so that continued, sustained commitments – political, financial and social -- are high on the political agenda and we will increase accountability for follow-through. The world is at risk. But, collectively, we already have the tools to save ourselves and our economies.

What we need is leadership and the willingness to act forcefully and effectively.

ACTIONS FOR LEADERS TO TAKE

The world requires determined political leadership to prepare for health threats at national and global levels. The GPMB calls for:

SEVEN URGENT ACTIONS TO PREPARE THE WORLD FOR HEALTH EMERGENCIES

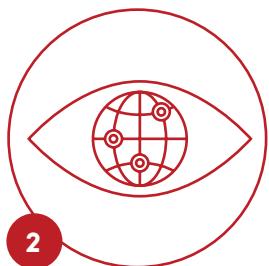


Heads of government must commit and invest.

Heads of government in every country must commit to preparedness by implementing their binding obligations under the International Health Regulations (IHR (2005)). They must prioritize and dedicate domestic resources and recurrent spending for preparedness as an integral part of national and global security, universal health coverage and the Sustainable Development Goals (SDG).

Progress indicator(s) by September 2020

- All countries that have completed an assessment of their capacities by 1 July 2019 have developed a costed National Action Plan for Health Security (NAPHS), identified required resources and started to implement the plan.

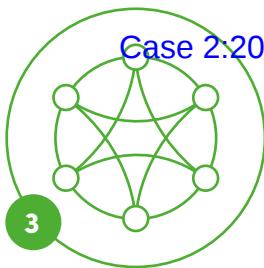


Countries and regional organizations must lead by example.

G7, G20 and G77 Member States, and regional intergovernmental organizations must follow through on their political and funding commitments for preparedness and agree to routinely monitor progress during their annual meetings.

Progress indicator(s) by September 2020

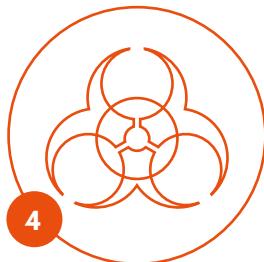
- G7, G20, G77 and regional intergovernmental organizations monitor their commitments to preparedness for health emergencies.



Heads of government must appoint a national high-level coordinator with authority and political accountability to lead whole-of-government and whole-of-society approaches, and routinely conduct multisectoral simulation exercises to establish and maintain effective preparedness. They must prioritize community involvement in all preparedness efforts, building trust and engaging multiple stakeholders (e.g. legislators; representatives of the human and animal health, security and foreign affairs sectors; the private sector; local leaders; and women and youth).

Progress indicator(s) by September 2020

- At a minimum, the 59 countries that have completed a NAPHS identify a national high-level coordinator (board, commission or agency) to implement national preparedness measures across all sectors, and to lead and direct actions in these sectors in the event of a public health emergency.
- WHO, the World Bank and partners, working with countries, develop and cost packages of priority interventions to increase preparedness capacity that can be financed in current budget cycles and map these interventions to expected results in the near term.
- There are fewer, but better harmonized coordination mechanisms, global, regional and country networks, institutions and initiatives for preparedness and readiness and for research and development (R&D).



Countries, donors and multilateral institutions must be prepared for the worst.

A rapidly spreading pandemic due to a lethal respiratory pathogen (*whether naturally emergent or accidentally or deliberately released*) poses additional preparedness requirements. Donors and multilateral institutions must ensure adequate investment in developing innovative vaccines and therapeutics, surge manufacturing capacity, broad-spectrum antivirals and appropriate non-pharmaceutical interventions. All countries must develop a system for immediately sharing genome sequences of any new pathogen for public health purposes along with the means to share limited medical countermeasures across countries.

Progress indicator(s) by September 2020

- Donors and countries commit and identify timelines for: financing and development of a universal influenza vaccine, broad spectrum antivirals, and targeted therapeutics. WHO and its Member States develop options for standard procedures and timelines for sharing of sequence data, specimens, and medical countermeasures for pathogens other than influenza.
- Donors, countries and multilateral institutions develop a multi-year plan and approach for strengthening R&D research capacity, in advance of and during an epidemic.
- WHO, the United Nations Children's Fund, the International Federation of Red Cross and Red Crescent Societies, academic and other partners identify strategies for increasing capacity and integration of social science approaches and researchers across the entire preparedness/response continuum.



To mitigate the severe economic impacts of a national or regional epidemic and/or a global pandemic, the International Monetary Fund (IMF) and the World Bank must urgently renew their efforts to integrate preparedness into economic risk and institutional assessments, including the IMF's next cycle of Article IV consultations with countries and the World Bank's next Systematic Country Diagnostics for International Development Association (IDA) credits and grants. Funding replenishments of the IDA, Global Fund to Fight AIDS, TB and Malaria (Global Fund), and Gavi should include explicit commitments regarding preparedness.

Progress indicator(s) by September 2020

- The IMF and the World Bank integrate preparedness in their systematic country risk, policy and institutional assessments, including in Article IV staff reports and for IDA credits/grants respectively.
- International funding mechanisms expand their scope and envelopes to include health emergency preparedness, including the IDA19 replenishment, the Central Emergency Response Fund, Gavi, the Global Fund and others.



Development assistance funders must create incentives and increase funding for preparedness.

Donors, international financing institutions, global funds and philanthropies must increase funding for the poorest and most vulnerable countries through development assistance for health and greater/earlier access to the United Nations Central Emergency Response Fund to close financing gaps for their national actions plans for health security as a joint responsibility and a global public good. Member states need to agree to an increase in WHO contributions for the financing of preparedness and response activities and must sustainably fund the WHO Contingency Fund for Emergencies, including the establishment of a replenishment scheme using funding from the revised World Bank Pandemic Emergency Financing Facility.

Progress indicator(s) by September 2020

- WHO member states agree to an increase in contributions for preparedness at the Seventy-third World Health Assembly in 2020; and Member States, the World Bank and donors provide sustainable financing for the Contingency Fund for Emergencies to a level of US\$ 100 million annually.



The United Nations must strengthen coordination mechanisms.

The Secretary General of the United Nations, with WHO and United Nations Office for the Coordination of Humanitarian Affairs (OCHA), must strengthen coordination in different country, health and humanitarian emergency contexts, by ensuring clear United Nations systemwide roles and responsibilities; rapidly resetting preparedness and response strategies during health emergencies; and, enhancing United Nations system leadership for preparedness, including through routine simulation exercises. WHO should introduce an approach to mobilize the wider national, regional and international community at earlier stages of an outbreak, prior to a declaration of an IHR (2005) Public Health Emergency of International Concern.

Progress indicator(s) by September 2020

- The Secretary-General of the United Nations, with the Director-General of WHO and Under-Secretary-General for Humanitarian Affairs strengthens coordination and identifies clear roles and responsibilities and timely triggers for a coordinated United Nations systemwide response for health emergencies in different countries and different health and humanitarian emergency contexts.
- **The United Nations (including WHO) conducts at least two system-wide training and simulation exercises, including one for covering the deliberate release of a lethal respiratory pathogen.**
- WHO develops intermediate triggers to mobilize national, international and multilateral action early in outbreaks, to complement existing mechanisms for later and more advanced stages of an outbreak under the IHR (2005).
- The Secretary General of the United Nations convenes a high-level dialogue with health, security and foreign affairs officials to determine how the world can address the threat of a lethal respiratory pathogen pandemic, as well as for managing preparedness for disease outbreaks in complex, insecure contexts.



A world at risk

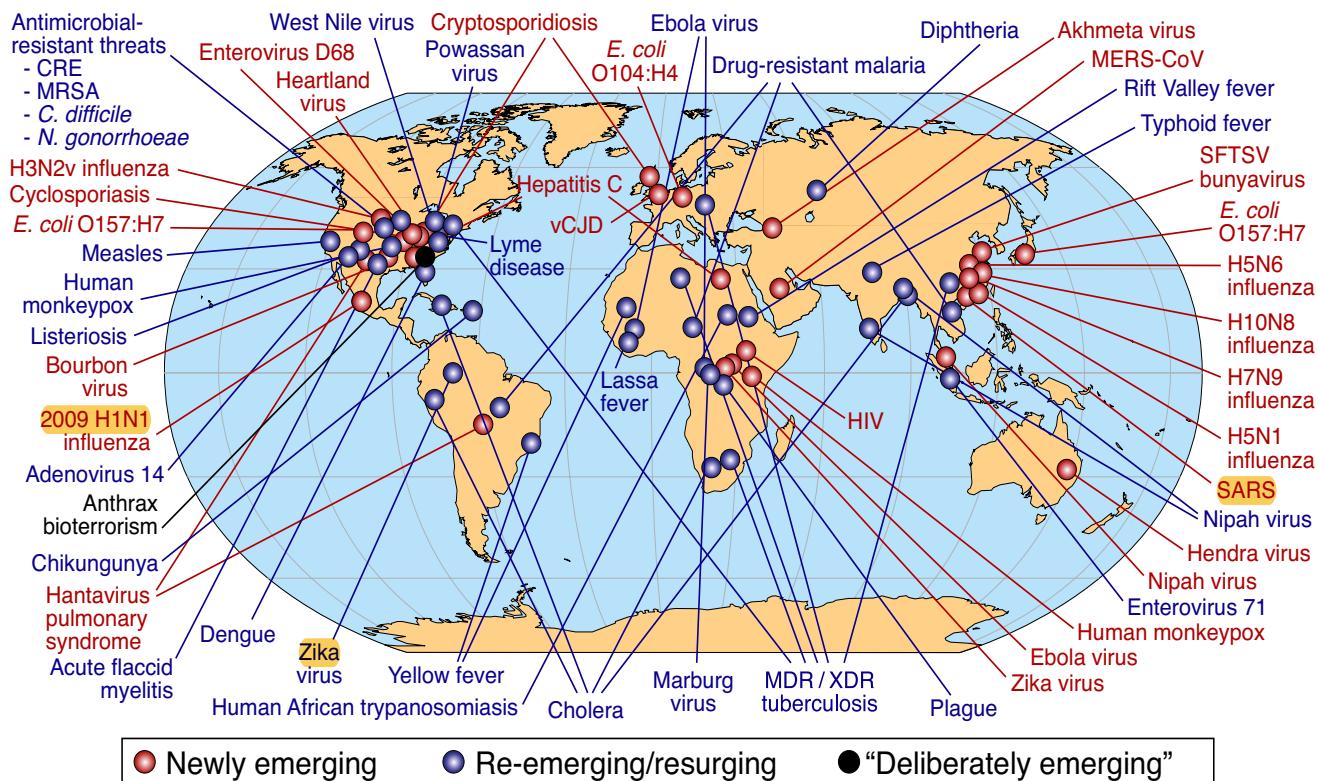
The world is at acute risk for devastating regional or global disease epidemics or pandemics that not only cause loss of life but upend economies and create social chaos.

Vulnerability is heightened by an increase in outbreaks occurring in complex humanitarian emergencies, as well as a novel convergence of ecological, political, economic and social trends including population growth, increased urbanization, a globally integrated economy, widespread and faster travel, conflict, migration and climate change (2). Specific risks are described below:

The world is confronted by increasing infectious disease outbreaks.

Between 2011 and 2018, WHO tracked 1483 epidemic events in 172 countries³. Epidemic-prone diseases such as influenza, Severe Acute Respiratory Syndrome (SARS), Middle East Respiratory Syndrome (MERS), Ebola, Zika, plague, Yellow Fever and others, are harbingers of a new era of high-impact, potentially fast-spreading outbreaks that are more frequently detected and increasingly difficult to manage. Fig. 1 demonstrates the global emergence of selected pathogens over the past 50 years, including both those that naturally emerge/re-emerge and those that are deliberately released.

FIGURE 1 Global examples of emerging and re-emerging diseases



C. difficile: Clostridium difficile; CRE: carbapenem-resistant Enterobacteriaceae; *E. coli*: Escherichia coli; MDR: multidrug-resistant [tuberculosis]; MERS-CoV: Middle East respiratory syndrome coronavirus; MRSA: methicillin-resistant Staphylococcus aureus; *N. gonorrhoeae*; *Neisseria gonorrhoeae*; SFTSV: severe fever with thrombocytopenia syndrome virus; XDR: extensively drug-resistant [tuberculosis].

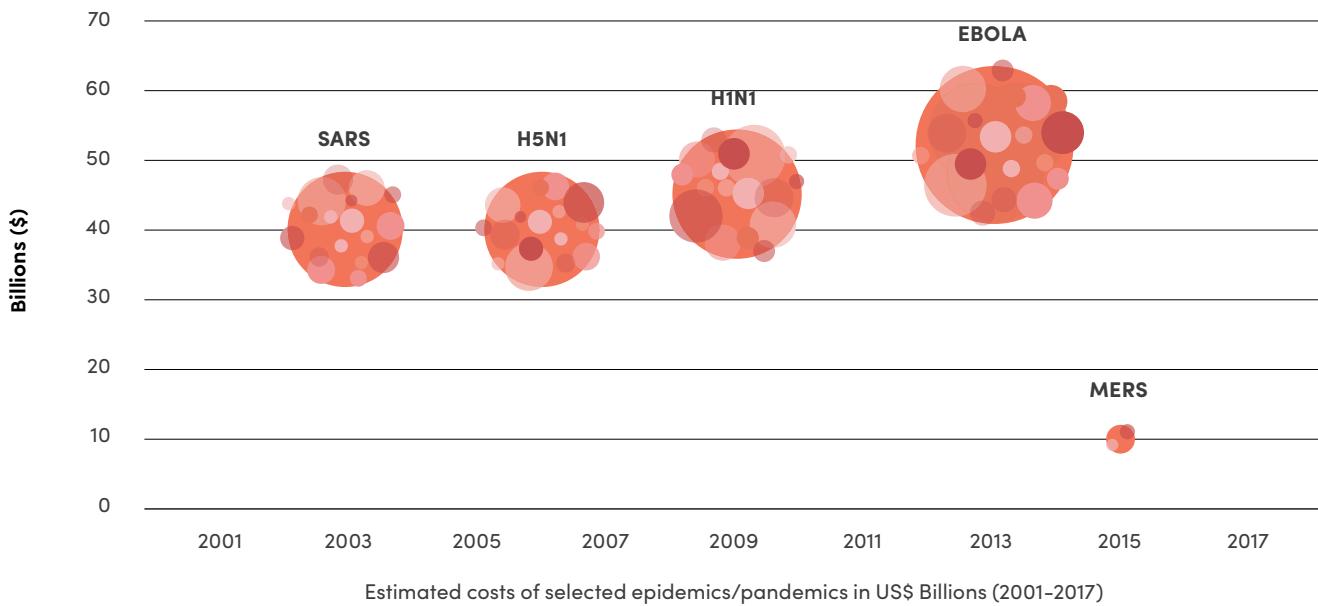
Source: United States National Institutes of Health, National Institute for Allergies and Infectious Diseases (4).

Any country without basic primary health care, public health services, health infrastructure and effective infection control mechanisms faces the greatest losses, including death, displacement and economic devastation. Disease outbreaks disrupt the entire health system reducing access to health services for all diseases and conditions, which leads to even greater mortality and further economic depression. Negative impacts are particularly profound in fragile and vulnerable settings, where poverty, poor governance, weak health systems, lack of trust in health services, specific cultural and religious aspects and sometimes ongoing armed conflict greatly complicate outbreak preparedness and response.

All economies are vulnerable.

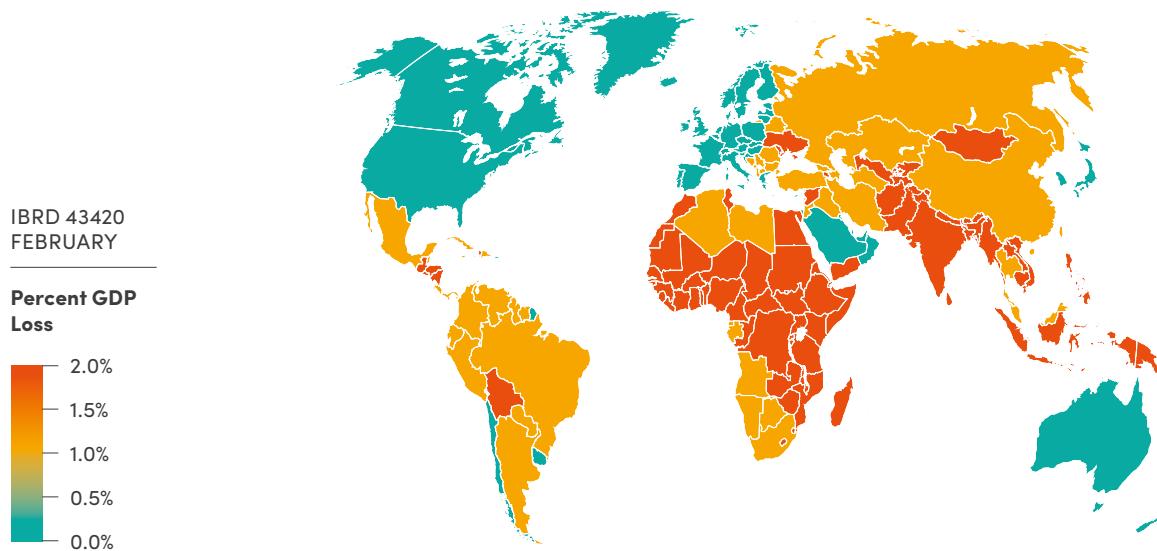
In addition to loss of life, epidemics and pandemics devastate economies. Estimated costs of past events include: a loss of over US \$40 billion in productivity from the 2003 SARS epidemic (5); US\$53 billion loss from the economic and social impact of the 2014–2016 West Africa Ebola outbreak (6,7); and the US\$ 45 to 55 billion cost of the 2009 H1N1 influenza pandemic⁸ (Fig. 2). The World Bank estimates that a global influenza pandemic akin to the scale and virulence of the one in 1918 would cost the modern economy US\$ 3 trillion, or up to 4.8% of gross domestic product (GDP); the cost would be 2.2% of GDP for even a moderately virulent influenza pandemic (9). Models predict the annual cost of a global influenza pandemic would mean that South Asia's GDP would drop by 2% (US\$ 53 billion), and Sub-Saharan Africa's GDP by 1.7% (US\$ 28 billion), the latter equivalent to erasing a full year's economic growth (Fig. 3) (10,11,12).

FIGURE 2 Costs of selected epidemics (US\$ billions)



Source: Resolve to Save Lives (www.resolvetosavelives.org).

FIGURE 3 Predicted country vulnerability to pandemic economic loss, 2018 (% GDP loss)
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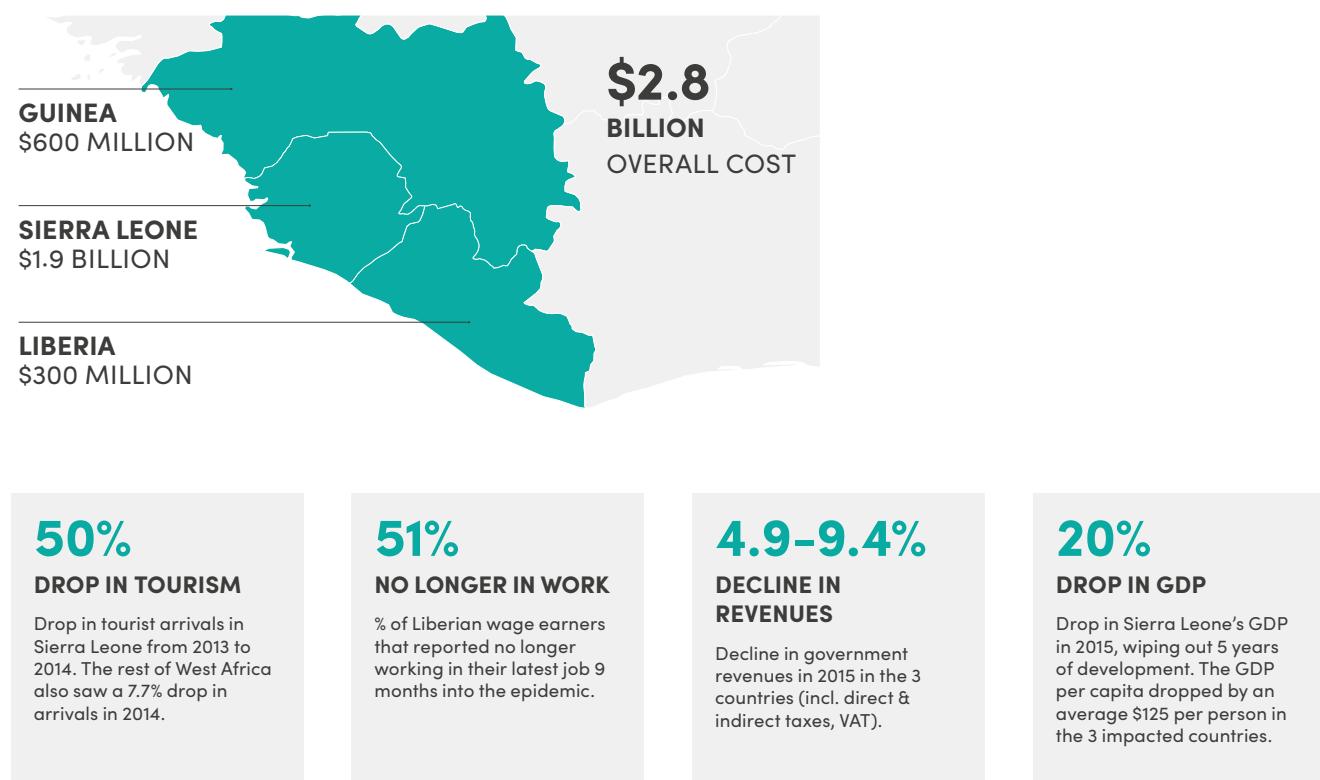


IBRD: International Bank for Reconstruction and Development.

Source: Resolve to Save Lives (www.resolvetosavelives.org).

The direct impacts on countries are severe. Guinea, Liberia and Sierra Leone lost an estimated US\$ 2.2 billion in GDP in 2015 (13) during the 2014–2016 West Africa Ebola outbreak (14) (Fig. 4).

FIGURE 4 Costs of 2014–2016 Ebola epidemic, West Africa (US\$)



Source: Resolve to Save Lives (www.resolvetosavelives.org).

- Global merchandise trade estimated at US\$ 17.43 trillion
- Commercial services, including tourism: US\$ 5.19 trillion.

Combined, they made up about 18% of the global economy.

- The world has become closely interconnected in terms of value chains and population movement, and not only for rich countries. The share of trade held by developing economies:
 - merchandise exports: 44% (almost half as trade among these countries).
 - commercial services, including tourism: 34%

The chances of a global pandemic are growing. While scientific and technological developments provide new tools that advance public health (including safely assessing medical countermeasures), they also allow for disease-causing microorganisms to be engineered or recreated in laboratories. A deliberate release would complicate outbreak response; in addition to the need to decide how to counter the pathogen, security measures would come into play limiting information-sharing and fomenting social divisions. Taken together, naturally occurring, accidental, or deliberate events caused by high-impact respiratory pathogens pose “global catastrophic biological risks.” (15)

The world is not prepared for a fast-moving, virulent respiratory pathogen pandemic. The 1918 global influenza pandemic sickened one third of the world population and killed as many as 50 million people - 2.8% of the total population (16,17). If a similar contagion occurred today with a population four times larger and travel times anywhere in the world less than 36 hours, 50 - 80 million people could perish (18,19). In addition to tragic levels of mortality, such a pandemic could cause panic, destabilize national security and seriously impact the global economy and trade.

Trust in institutions is eroding. Governments, scientists, the media, public health, health systems and health workers in many countries are facing a breakdown in public trust that is threatening their ability to function effectively. The situation is exacerbated by misinformation that can hinder disease control communicated quickly and widely via social media.

COMMUNITY HAVE MADE PROGRESS IN PREPARING TO FACE HEALTH EMERGENCIES

... BUT CURRENT EFFORTS REMAIN GROSSLY
INSUFFICIENT.

In the next section, the Board lists examples of progress and persistent challenges in the following categories:

- 1. Leadership drives progress**
- 2. Building effective systems**
- 3. Preparing for the worst: a rapidly spreading lethal respiratory pathogen pandemic**
- 4. Financing**
- 5. International coordination mechanisms**

The Board proposes seven urgent actions that national and global leaders must take to prepare for health emergencies. Some aspects of these actions can be achieved in the next year, and the Board challenges political leaders to move forward on these rapidly.

What is preparedness?

The United Nations and WHO define preparedness as the ability (knowledge, capacities, and organizational systems) of governments, professional response organizations, communities and individuals to anticipate, detect and respond effectively to, and recover from, the impact of likely, imminent or current health emergencies, hazards, events or conditions. It means putting in place mechanisms that will allow national authorities, multilateral organizations and relief organizations to be aware of risks and deploy staff and resources quickly once a crisis strikes (20,21).



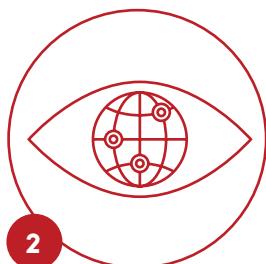
Progress, challenges, actions



Leadership drives progress



National and local leaders are responsible for ensuring preparedness from the country to the community level. Action and investment prior to an emergency are essential to provide the best possible protection. Ensuring recurrent spending for preparedness is a key articulation of political will and leadership. Long-term, sustained community engagement is crucial for detecting outbreaks early, controlling amplification and spread, ensuring trust and social cohesion, and fostering effective responses.



In addition to their domestic responsibilities, national leaders have preparedness obligations to the world at large.ⁱ All countries have adopted the binding International Health Regulations (IHR (2005), a treaty requiring governments to develop national core capacities to detect, assess, report and respond to health threats, as well as to report any “public health emergency of international concern” to WHO and to take corresponding action (22).

Regional and global leaders must support country actions and develop networks of partners to aid in preparedness and disease control.

Although, the contexts and drivers for increased frequency and severity of epidemics and pandemics are increasingly complex, leaders can plan and galvanize robust preparedness for their communities, countries, and for the world through determined measures.

i. These obligations include maintaining effective disease surveillance and laboratory systems; reporting newly emerging diseases that could spread internationally; and maintaining the necessary infrastructure to respond to health emergencies. See <https://www.who.int/ihr>.

Progress to date

- Each country has identified an IHR focal point to manage IHR-related reporting requirements in keeping with their commitments under the IHR (2005). National assessments and planning have improved considerably: as of July 2019, 190 countries reported their progress in implementing IHR (2005) in 2018, using the State Party self-assessment annual reporting (SPAR) tool; 102 countries have conducted a voluntary Joint External Evaluation (JEE)ⁱⁱ, 103 countries have conducted simulation exercises, 51 countries have completed after-action reviews, 59-countries developed a National Action Plan for Health Security (NAPHS) and 51 have costed them (23).
- Recognizing the shared threat of a global health catastrophe, national leaders have undertaken political actions to advance preparedness. Political bodies, such as the G7, G20 (24), G77 and several regional intergovernmental organizations such as the African Union (25) have adopted political commitments for action on various aspects of health and health emergencies, including funding and linkages to health systems strengthening and universal health coverage. The G77 foreign ministers recognized that outbreaks of epidemics or other global health threats deserved to be given the same level of attention as other serious threats confronting countries (26).
- The Global Health Security Agenda (GHSA), a multi-country coalition launched in early 2014 aims to increase country level capacities and coordination for disease detection, prevention and control, has grown to nearly 70-member countries and partner organizations (27). Its Private Sector Roundtable is working with industry to enhance the latter's participation in global health security.
- Multilateral institutions and donors have acted to prepare for the worst pandemic challenges. At the global level, in addition to the IHR (2005) and further recommendations for their improvement adopted in 2009 and 2016, (28) health leaders have developed the Pandemic Influenza Preparedness (PIP) Framework to address virus-sharing and benefit-sharing concerns arising from the 2006 H5N1 outbreak.
- In 2017 Germany, India, Japan, Norway, the Bill & Melinda Gates Foundation, the Wellcome Trust and the World Economic Forum founded the Coalition for Epidemic Preparedness Innovations (CEPI) to facilitate focused support for vaccine development to combat major health epidemic/pandemic threats.

ii. A WHO managed process where countries undertake a voluntary, multisectoral assessment of their core capacities under IHR (2005), with national self-assessment and an external evaluation team with experts, See <https://www.who.int/ihr/procedures/joint-external-evaluations/en/>.

Persistent challenges and obstacles

Insufficient national and local leadership

Preparedness is hampered by the lack of continued political will at all levels. Although national leaders respond to health crises when fear and panic grow strong enough, most countries do not devote the consistent energy and resources needed to keep outbreaks from escalating into disasters.

Weak compliance with the IHR (2005)

As of 2018, only one-third of countries have the capacities required under the IHR (2005) (29). While progress has been achieved in many higher income countries, low- and middle-income countries struggle with funding these functions. Not only does this impact their own ability to respond to outbreaks, it puts the whole world at risk. The great majority of national health systems would be unable to handle a large influx of patients infected with a respiratory pathogen capable of easy transmissibility and high mortality.

Inadequate international support for preparedness in the poorest countries

Although G7, G20, G77 and regional intergovernmental organization leaders have made a number of commitments to health and preparedness in recent years, follow-through is lacking. Collective security and the performance of international health systems in an increasingly globalized world are only as “strong as their weakest link.” For example, although the G7 has committed to supporting 76 countries in building their IHR (2005) core capacities in four separate meetings (30), G7 Member States have not monitored the follow-up to these commitments.

Required actions

Heads of government must commit and invest

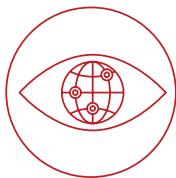


Heads of government in every country must commit to preparedness by implementing their binding obligations under the IHR (2005). They must prioritize and dedicate domestic resources and recurrent spending for preparedness as an integral part of national and global security, universal health coverage and the Sustainable Development Goals (SDG).

Progress indicator(s) by September 2020

- All countries that have completed an assessment of their capacities by 1 July 2019 have developed a costed NAPHS, identified required resources and started to implement the plan.

Countries and regional organizations must lead by example



G7, G20 and G77 Member States and regional intergovernmental organizations must follow through on their political and funding commitments to preparedness and agree to routinely monitor progress at their annual meetings.

Progress indicator(s) by September 2020

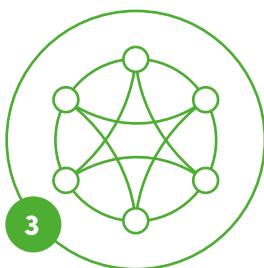
- G7, G20, G77 and regional intergovernmental organizations monitor their commitments to preparedness for health emergencies.

Ultimate objectives

All countries have reached full compliance with IHR (2005), have completed voluntary external or other independent assessments, and are objectively monitored by WHO on a regular basis to ensure continued improvement in preparedness. Recurrent national spending for preparedness is secured. Follow-up of countries' political and funding commitments made before G7, G20, G77 and regional organizations are monitored routinely.



Building effective systems



Planning for emergencies creates a virtuous cycle, whereby preparedness enables a successful response and from which built capacities and knowledge gained during an outbreak become the foundation to prepare for the next threat. Setting up these arrangements will require prioritizing systems-building across the whole society, in a variety of contexts, testing different models, and creating environments and mechanisms for sharing best practices, among countries at all economic levels.

Effective, accessible and efficient local health systems delivering primary health care, and mental health and psychosocial services essential for prevention will also yield multiple benefits beyond preparedness, including infectious disease prevention and control, better health outcomes and increased community trust, as well as surge response capacity. When a health emergency strikes, national and regional authorities need to be able to count on a global backup system that is well resourced, well-coordinated and well-practised.

Every country and community must be prepared for the unexpected.

Progress to date

- Timeliness in detection of outbreaks has increased significantly, as shown by the swift declaration of the 2016 outbreak of Zika, the 2018 outbreak of Ebola in the Democratic Republic of the Congo (DRC), and the first Ebola cases in Uganda. Rapid detection, isolation and treatment of recent Ebola cases in Uganda reflect better preparedness planning and investments. In addition, nine countries neighbouring the eastern DRC have enhanced their preparedness efforts.
- As part of IHR (2005) monitoring, 103 simulation exercises and 50 after-action reviews have been conducted, and 26 countries have an IHR (2005)-Performance of Veterinary Services national bridging workshop (31,32).
- **China, Nigeria and the WHO African and Eastern Mediterranean regions, among others, have developed public health organizations/institutes and training programmes modelled on successful programmes and agencies.**
- A number of Member States of the Commonwealth of Independent States Countries and those active in the European Environment and Sustainable Development Advisory Councils have increased their surveillance and laboratory capacities, including rapid operational engagement of mobile medical teams.
- At the global level, the new Health Emergencies Programme established at the World Health Organization (WHO) following the 2014-2016 Ebola crisis in west Africa enabled the organization to take on a stronger, more effective operational role in outbreaks. The reforms have already made a significant difference in emergency response worldwide.
- There is increased awareness of the need for community involvement in all aspects of preparedness. Recent outbreaks of Ebola and Zika, and other diseases saw calls for an increase in community engagement in view of its high effectiveness. WHO's new IHR (2005) monitoring framework has expanded by including risk communication and community engagement assessments.
- Political will, financial investment and health system improvements lead to results. For example, the Republic of Korea successfully contained a second potential MERS outbreak in 2018; before the 2014-2016 outbreak of Ebola virus disease in west Africa, Nigeria implemented an epidemic preparedness infrastructure that resulted in rapid control of Ebola cases and cost savings compared with experiences of its neighbours (33); and recent improvements in India's health system helped that country identify and contain the deadly Nipah virus diagnosed in Kerala in May 2018.

Persistent challenges and obstacles

Poor integration between preparedness and day to day health needs

Too many places lack even the most rudimentary health-care infrastructure. Communities that cannot care for a pregnant woman and her newborn child cannot protect against a disease outbreak.

A clear national leader for pandemic preparedness and response is too often identified only after the onset of a crisis

In the ongoing Ebola response, and for Zika, influenza and other outbreaks in many countries, the national and international leads have been identified after the fact, or changed in mid-course, causing delays in decision making. Leadership should be clearly identified in advanced, authorized and held accountable for preparedness.

Country coordinating mechanisms for health emergency preparedness are not broad enough

Although the IHR (2005) requirements are instrumental, they need to be expanded to sectors beyond health to create a broad continuum of preparedness. As a case in point, only four of the 197 national focal points are located outside the country's Ministry of Health. As potential models, a number of countries have national multisectoral coordination entities to deal with natural disasters, as well as those created to fight against HIV/AIDS.

Whole-of-government and whole-of-society system planning and engagement for preparedness are frequently lacking

Efforts on national and local preparedness planning too often lack an effective "whole-of-government" and "whole-of-society" approach. Other parties that must be engaged include national agencies beyond the health ministry, local governments, traditional and religious leaders, civil society, the research and security communities, the private sector, the media and operational experts. Preparedness-specific and preparedness-sensitive activities need to be included in sector specific strategies and systems-strengthening plans, such as those for universal health coverage; animal health in agriculture and livestock; transport and security; and disaster risk management.

Monitoring is incomplete and infrequent

Repeat assessments to monitor progress for JEEs are not yet in place. IHR (2005) SPAR reporting is done by self-reporting in countries. Additional assessment tools are needed to allow identification of weaknesses in preparedness before a health emergency occurs.

Grossly insufficient involvement of communities in all aspects of preparedness

Community engagement across all aspects of national preparedness planning and response is fundamentally lacking. It is essential to understand community needs and ensure their systematic incorporation into planning and accountability mechanisms. Currently, these needs are not well assessed nor integrated into country and WHO preparedness approaches.

Inadequate inclusion of women and youth

Sustainable preparedness requires involvement of women and youth in planning and decision-making. The majority of both formal and informal care givers are women, and their engagement ensures that policies and interventions are accepted and that they have full access to the services provided. It is important to ensure that the basic health needs of women and girls, including those for reproductive health, are met during an outbreak.

Breakdown of trust and social cohesion

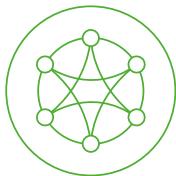
Challenges to poliomyelitis (polio) eradication efforts in Afghanistan and Pakistan and those experienced while containing the tenth Ebola outbreak in the DRC vividly demonstrate the impact that a breakdown in citizens' trust and social cohesion can have on health emergency response. Consequences include attacks on both national and international health-care workers and delays or stoppages in response efforts. In some countries, waning trust in public health and government officials together with cultural and religious beliefs lead to is decreasing vaccination rates and leading to the re-emergence of measles and other vaccine-preventable diseases, a phenomenon found in communities at all economic and educational levels.

Existing health system and disease control assets are not maximized to support preparedness:

Many financial, human, infrastructure, surveillance and laboratory health resources already exist in countries that can directly support preparedness efforts. However, resources for disease-specific programmes, such as those for HIV, tuberculosis, malaria and polio eradication, often do not include or sustainably support preparedness. For example, entities providing funding and programmatic support for countries, such as the Global Fund to Fight AIDS, TB and Malaria (Global Fund) and Gavi, do not explicitly include prevention and preparedness to achieve broader health security. The Global Polio Eradication Initiative has developed extensive laboratory and disease surveillance networks focused on poliovirus detection and identification, but this capacity is not leveraged sufficiently for broader health monitoring. Whereas polio assets have supported other outbreak preparedness efforts (as seen with the outbreak of Ebola in Nigeria in 2014–2016), capacities are threatened, as funding will predictably wane once polio eradication is achieved.

Required actions

All countries must build strong systems



Heads of government must appoint a national high-level coordinator with authority and political accountability to lead whole-of-government and whole-of-society approaches, and routinely conduct multisectoral simulation exercises to establish and maintain effective preparedness. They must prioritize community involvement in all preparedness efforts, building trust and engaging multiple stakeholders (e.g. legislators; representatives of human and animal health, security, and foreign affairs sectors; the private sector; local leaders; and women and youth).

Progress indicator(s) by September 2020

- At a minimum, the 59 countries that have completed an NAPHS identify a national high-level coordinator (board, commission or agency) to implement national preparedness measures across all sectors and to lead and direct actions in these sectors in the event of a public health emergency.
- WHO, the World Bank and partners, working with countries, develop and cost packages of priority interventions to increase preparedness capacity that can be financed in current budget cycles and map these interventions to expected results in the near term.
- There are fewer, but better harmonized coordination mechanisms, global, regional and country networks, institutions and initiatives for preparedness and readiness and for research and development (R&D).

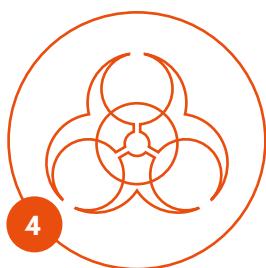
Ultimate objectives:

All countries have identified a high-level coordinator to plan and implement preparedness and response across all sectors, including health, security, finance and other relevant ministries. The coordinator demonstrates through exercises or actual events that national preparedness and response systems are capable of mitigating all types of public health emergencies. Preparedness activities involve communities in all phases of planning and implementation.



Preparing for the worst:

a rapidly spreading, lethal respiratory pathogen pandemic



High-impact respiratory pathogens, such as an especially deadly strain of influenza, pose particular global risks in the modern age. The pathogens are spread via respiratory droplets; they can infect a large number of people very quickly and with today's transportation infrastructure, move rapidly across multiple geographies.

In addition to a greater risk of pandemics from natural pathogens, scientific developments allow for disease-causing microorganisms to be engineered or recreated in laboratories. Should countries, terrorist groups, or scientifically advanced individuals create or obtain and then use biological weapons that have the characteristics of a novel, high-impact respiratory pathogen, the consequences could be as severe as, or even greater, than those of a natural epidemic, as could an accidental release of epidemic-prone microorganisms.

Progress to date

- WHO established the Research and Development (R&D) Blueprint to help organizations identify research needs and work with country partners to plan for and implement studies during epidemics (34).
- WHO Member States adopted the PIP Framework to improve pandemic influenza preparedness globally and support a more equitable response. Through the PIP Framework, WHO has supported countries financially and technically to improve certain essential public health capacities and established a virtual stockpile of pandemic influenza vaccines (currently estimated at more than 400 million doses). Global production capacity for influenza vaccines has increased to an estimated 6.4 billion doses (35).
- Bolstering pandemic influenza preparedness, the Global Influenza Surveillance and Response System has grown to 151 laboratories in 115 countries and has been commended repeatedly for timely identification, assessment and monitoring of influenza and other respiratory pathogens, including MERS and SARS.
- Funding for research has increased. While figures on R&D funding for epidemics are difficult to come by, studies show investment in research on neglected diseases rose by 7% between 2016 and 2017, representing a 10-year high. Over the last decade, national public-sector funding from low- and middle-income countries grew 17% (36). As of June 2019, CEPI has raised US\$ 750 million to develop vaccines to stop future epidemics (37).

Persistent challenges and obstacles

Lack of planning and readiness for a rapidly moving, lethal pandemic caused by a respiratory pathogen

Preparedness and response systems and capabilities for disease outbreaks are not sufficient to deal with the enormous impact, rapid spread and shock to health, social and economic systems of a highly lethal pandemic, whether natural, accidental or deliberately released. There is insufficient R&D investment and planning for innovative vaccine development and manufacture, broad-spectrum antivirals, appropriate non-pharmaceutical interventionsⁱⁱⁱ (38), targeted therapeutics (including monoclonal antibodies), systems for sharing sequences of any new pathogen, and means for equitably sharing limited medical countermeasures across countries. In addition, such a pandemic requires advance planning across multiple sectors (financial, security, transportation, logistics, global communications and industry), for reinforcing social cohesion and for risk communication. Epidemic control costs would completely overwhelm the current financing arrangements for emergency response.

iii. Non-pharmaceutical interventions include public safety protocols, school and business closures, airline and transportation protocols, communications protocols, supply chain readiness etc., as well as coordination between the public and private sectors, national and local authorities.

Lack of data sharing and medical countermeasures in the context of a Public Health Emergency of International Concern is unacceptable

The lack of optimized sample-sharing and information-sharing slows down the public health response and R&D. The PIP framework is limited to pandemic influenza, and there are no frameworks for other infectious diseases with pandemic potential. Concerns exist regarding the impact of the Nagoya Protocol (39) on timely sharing of pathogen samples (40).

Limited medical countermeasures are shared inequitably at times and are likely to be prioritized for domestic use during a pandemic. Countries need to trust that, if they share samples and data, they will have access to any advances that result from them.

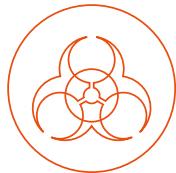
Research and development, key to developing medical countermeasures and effective preparedness, have major systemic problems

These problems include (41):

- **National capacities are not well developed for research and development, including during outbreaks, as well as for deployment of vaccines, therapeutics, diagnostics, and other medical countermeasures, and creating new vaccine manufacturing methods.** Country research approaches, regulatory, ethics and operational capacities require strengthening. Despite some promising developments, the technologies used for influenza vaccines production have remained almost unchanged since the 1960s, are expensive and time-consuming, and would constitute a serious bottleneck in the event of a pandemic. For other respiratory pathogens, very little progress has been made in developing medical countermeasures.
- **Research infrastructure and level/predictability of funding are weak.** Overall funding remains too low, with sustained investment hampered by the high costs of R&D and high probability of failure. The bulk of R&D funding and activities, including research on neglected tropical diseases, remains in high income countries. While these investments are laudable, research agendas in these countries may not always reflect low income country needs (e.g. development of Ebola countermeasures in developed countries used for biodefence).
- **More resources have gone into vaccines, basic research and therapeutics than into diagnostic advances.** Attention to diagnostics is important not just for treatment of individuals, but also to assess efficacy of vaccines and treatments and to gauge the speed and breadth of disease spread.
- **Social science research is poorly integrated into national and international research portfolios, and not applied to preparedness.**

Required actions

Countries, donors and multilateral institutions must be prepared for the worst



A rapidly spreading pandemic due to a lethal respiratory pathogen (*whether naturally emergent or accidentally or deliberately released*) poses additional preparedness requirements. Donors and multilateral institutions must ensure adequate investment in development of innovative vaccine and therapeutics, surge manufacturing capacity, broad-spectrum antivirals and appropriate non-pharmaceutical interventions. All countries must develop a system for immediately sharing sequences of any new pathogen for public health purposes, along with the means to share limited medical countermeasures across countries.

Progress indicator(s) by September 2020

- Donors and countries commit and identify timelines for: financing and development of a universal influenza vaccine, broad-spectrum antivirals and targeted therapeutics. WHO and its Member States develop options for standard procedures and timelines for sharing of sequence data, specimens and medical countermeasures for pathogens other than influenza.
- Donors, countries and multilateral institutions develop a multiyear plan and approach for strengthening R&D research capacity, in advance of and during an epidemic.
- WHO, the United Nations Children's Fund, the International Federation of Red Cross and Red Crescent Societies, academic and other partners identify strategies for increasing capacity and integration of social science approaches and researchers across the entire preparedness/response continuum.

Ultimate objectives:

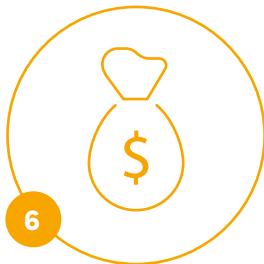
The tools and systems needed to respond effectively to a fast-moving and lethal respiratory pathogen are in place: A universal influenza vaccine is effective and routinely used to protect the global population; new therapeutics and broad-spectrum antivirals are widely available to treat and reduce mortality from a range of viruses; novel pathogens are routinely identified and sequenced, and the sequences are shared on a globally accessible website. Distributed manufacturing of vaccines (including nucleic acid types) begins within days of obtaining the new sequences and effective vaccines are pre-tested and approved for use within weeks.



Financing



Even the most conservative models suggest that pandemic risks are on par with other high-profile economic threats, including climate change (0.2-2.0% of global GDP, according to the Intergovernmental Panel on Climate Change 2014) or natural disasters (0.3-0.5% of global GDP and 65,000 deaths per year) (42). The International Monetary Fund's threshold for a major economic disaster is 0.5% of GDP loss (43).



Despite the high cost-benefit ratio of emergency preparedness, governments continue to neglect it. World Bank and WHO analyses indicate that most countries would need to spend on average between US\$ 1-US\$ 2 per person per year to reach an acceptable level of pandemic preparedness (44,45). Considering the benefits to economic growth (not counting the enormous cost to human life), investing in health systems to implement the IHR (2005) would yield a positive return on investment in all plausible scenarios (46). A yearly investment of US\$ 1.9-3.4 billion to strengthen animal and human health systems would yield an estimated global public benefit of more than US\$ 30 billion annually (47), a return on investment of 10 to 1 or higher (48). Preparedness capacities and systems are global public goods-all countries benefit from every country's investment.

Not investing is a high-risk gamble, given the potential economic and response costs.

Progress to date

- Some countries and parts of the international community are increasingly recognizing preparedness capacity as a critical part of wider public health systems strengthening and the universal health coverage agenda (49). For example: Senegal created a budget line to support the operating costs of its emergency operations centre; and The Greater Mekong Sub-region Health Security Project began working with the governments of Cambodia, the Lao People's Democratic Republic, Myanmar and Vietnam to improve preparedness for infectious diseases and other health threats.
- Regional initiatives have also increased funding for preparedness, including the following:
 - the Africa Centres for Disease Control and Prevention (US\$ 35 million, 2017–2018) developed a five-year strategic plan that provides the rationale for external funders to consider significant direct or parallel financial support;
 - the West Africa Regional Disease Surveillance Systems Enhancement Project (US\$ 390.8 million, 2016–2018), is supporting 11 West African countries in increasing national, regional and cross-sectoral capacity for integrated disease surveillance and response;
 - the Indo-Pacific Health Security Initiative invested in product development partnerships to accelerate research on new drugs and diagnostics and applied health systems.
- Ten countries conducted cross-cutting mapping of NAPHS and other health plans and domestic and bilateral/multilateral aid flows, identifying synergies and funding: for example, in Sierra Leone, the exercise identified US\$ 47.7 million across eight Ministries and external donors for two-year implementation of the NAPHS (50).
- International financial institutions have begun to prioritize preparedness:
 - WHO established the Contingency Fund for Emergencies (CFE) to respond immediately, within the critical first 24–48 hours, to a disease outbreak and humanitarian crises; since its launch in 2015. The CFE has enabled WHO to respond rapidly to 70 separate events in 48 countries (51);
 - the World Bank developed the Pandemic Emergency Financing Facility (PEF) to make pay-outs early during an outbreak cycle-before it becomes a pandemic-through two windows, insurance and cash; funding requests are assessed based on three criteria- pathogen type, epidemiological thresholds and a technical assessment (52);
 - the World Bank Group, including IDA, has taken steps to develop not only financing, but the political support and coordination needed to build clinical research capacity in developing countries as a crucial component of global epidemic preparedness (53).

Persistent challenges and obstacles

Financing systems for preparedness are broken, particularly at the national level

More and better-targeted funding is required at all levels starting with national governments. Too many national leaders have not prioritized spending on health systems overall and on preparedness in particular. Preparedness investments is also poorly differentiated from other aspects of health system strengthening.

National action plans for health security lack domestic financing

Success in national preparedness rests upon the ability of countries to identify systems gaps, develop their plans and finance them. Despite significant progress in assessing deficiencies and developing plans, **not a single NAPHS has been fully financed** (54). Without domestic resources, countries cannot redress the gaps, and momentum in national planning may stall or reverse.

International financing to poorest countries is insufficient, and available funds are not well-utilized

Resource constrained countries are unlikely to finance their NAPHS fully from domestic resources alone. With US\$ 75 billion available, the current IDA18 replenishment has met its target of supporting preparedness plans in 25 countries, yet most poor countries will not elect to use their finite IDA envelopes for preparedness given the trade-offs with other development priorities.

Insufficient rapid financing is available for preparedness and rapid response surge capacity

Existing financing mechanisms are inadequate for prolonged outbreaks and would not suffice for a fast-moving global pandemic, particularly one involving a respiratory pathogen.

WHO is underfunded

WHO lacks the predictable, flexible and sustainable funding it needs to play its critical role in coordinating preparedness and response and supporting country health systems. Nearly 80% of the WHO budget is voluntary and highly earmarked, precluding holistic preparedness efforts and hindering WHO's ability to provide a global safety net. Following its use in early response to the current outbreak of Ebola in eastern DRC, the CFE is now depleted (55). A review of the intended purpose and use of expenditure from the CFE, along with lessons for its maximum efficiency and focus, would be useful.

The Pandemic Emergency Financing Facility is in need of reform

To date, the PEF-model is not working because of key design issues; notably its parametric criteria for the diseases covered were set too high for the release of the insurance mechanism (56,57). The World Bank is redesigning the PEF and expects a new model to be ready in mid-2020. This will need to allow greater flexibility and agility so that financing can be made available earlier in a broader range of outbreak situations.

Private sector resources remain largely untapped

Although businesses rely on economic and social stability and have valuable systems, including logistics and supply chains, that could contribute to preparedness efforts, the private sector has not been sufficiently engaged.

Need for investment cases and building donor confidence

A multipronged effort is required to create an environment where policy-makers and communities demand the planning and resources necessary for effective preparedness. There is a lack of long-term, holistic, costed resource mobilization plans for supporting preparedness. Decision-makers must engage the private sector and create investment cases showing preparedness for health emergencies in health systems, human health, animal health, disaster management and the environment.

Required actions

Financing institutions must link preparedness with economic risk planning.



To mitigate the severe economic impacts of a national, regional epidemic and/or a global pandemic, the IMF and the World Bank must urgently renew their efforts to integrate preparedness into economic risk and institutional assessments, such as the IMF's next cycle of Article IV consultations with countries, and the World Bank's next Systematic Country Diagnostics for IDA credits and grants. The funding replenishments of the IDA, Global Fund to Fight AIDS, TB and Malaria, the and Gavi Alliance should include explicit commitments regarding preparedness.

Progress indicator(s) by September 2020

- The IMF and the World Bank integrate preparedness into their systematic country risk, policy and institutional assessments, including in Article IV staff reports and for IDA credits/ grants respectively.
- International funding mechanisms expand their scope and envelopes to include health emergency preparedness, including the IDA19 replenishment, the Central Emergency Response Fund, Gavi, the Global Fund and others.

Development assistance funders must create incentives and increase funding for preparedness.



Donors, international financing institutions, global funds and philanthropy must increase funding for the poorest and most vulnerable countries, through development assistance for health and greater/earlier access to the United Nations Central Emergency Response Fund to close financing gaps for their national health security action plans as a joint responsibility and a global public good. Member States need to agree to an increase in WHO contributions for preparedness and response financing and must sustainably fund the WHO Contingency Fund for Emergencies, including the establishment of a replenishment scheme using funding from the revised World Bank Pandemic Emergency Financing Facility.

Progress indicator(s) by September 2020

- WHO member states agree to an increase in contributions for preparedness at the Seventy-third World Health Assembly in 2020; and Member States, the World Bank and donors provide sustainable financing for the CFE to a level of US\$ 100 million annually.

Ultimate objectives:

All countries have completed and fully funded their NAPHS with domestic resources, supplemented by international sources for the poorest countries. The overall level of funding for preparedness has increased. The IMF and World Bank have functioning systems for financially supporting country preparedness and for making funding rapidly available in emergencies. WHO is adequately funded and equipped to support countries' preparedness and to lead a global response to a public health emergency on any scale; and the CFE is sustainably financed by many contributors, including from the World Bank PEF.



International coordination mechanisms



While the responsibility for preparedness lies largely with local and national leaders, an effective international response system is an essential global safety net. As the accumulation of new global trends and challenges creates more complex health emergencies, the international community must be better prepared. Poverty, deprivation and weak health and government structures can amplify a disease outbreak into a wide-ranging humanitarian catastrophe that quickly grows beyond what national authorities can manage. While WHO leads the international response to any health emergency, it needs reliable, systematic backup from other United Nations agencies to address logistical and humanitarian developments that are beyond its scope to manage.

Progress to date

- The ongoing tenth Ebola outbreak in the DRC reveals the complex challenges facing global and national preparedness despite increased attention and progress in this area. Among the signs of progress, an apparently successful vaccine has been administered to 170 000 people as of July 2019, and therapeutic approaches (some studied in an earlier outbreak and some newly discovered) are available; strong engagement of the DRC Ministry of Health at the highest levels; rapid WHO deployment of a multidisciplinary incident management team; heightened preparedness levels in neighbouring countries; and use of innovative technologies (58).
- The Inter-Agency Standing Committee (IASC) activated its revised (April 2019) systemwide “Humanitarian Systemwide Scale-up for Infectious Disease Events” protocol to adjust humanitarian response already underway (59,60).

Persistent challenges and obstacles

International coordination

mechanisms are not fit for purpose for health emergencies in complex environments

New approaches for international preparedness and, ultimately response, are needed as insecure contexts, such as the Eastern DRC and Yemen, have blurred the lines between health and humanitarian emergencies. New agile approaches would systematically coordinate key multisectoral international actors for different parts of a response, in order to plan for, monitor, assess, and adjust activities in real time. Further, attention must be given to transition planning from response to long-term development, stability and sustainable development once the outbreak ends.

It is unclear who will be in charge

The Secretary General of the United Nations belatedly identified a lead for public health emergencies in the 2014–2016 West Africa Ebola crisis (the United Nations Mission for Ebola Emergency Response); on 23 May 2019, 10 months after the onset of the Ebola outbreak in eastern DRC, he appointed the United Nations Ebola Emergency Response Coordinator to oversee United Nations systemwide control efforts (61). In the 2009 H1N1 influenza pandemic the WHO Director General was more explicitly in charge, although the United Nations System Influenza Coordinator was also involved, which created confusion (62).

WHO coordination and convening mechanisms are stretched

WHO leadership for health emergencies derives from the IHR (2005), but its convening and coordinating mechanisms are not sufficient to provide fully cohesive support for broad capacity strengthening in countries and for global outbreak response, or to ensure greater accountability of global preparedness. In addition, WHO lacks the systematic support it needs from the United Nations more broadly to tackle issues like security and trade pact violations that are beyond its scope (63).

No intermediate system exists for declaration of health emergencies at an earlier state

The IHR (2005) provide very focused criteria for activation of global resources under the designation Public Health Emergency of International Concern (PHEIC). However, the system lags behind in its ability to mobilize national and international resources and guiding multisectoral action early in an outbreak. The use of the PHEIC system is misunderstood by many stakeholders. Once a PHEIC has been declared, specific actions follow, including sharing critical information for risk assessment, adjusting response plans and implementing temporary measures, as necessary. The role of the PHEIC is limited to the late stages of an outbreak's spread, and there are potential negative consequences resulting from a declaration (such as unilateral, ill-advised country actions to limit travel or trade) (64,65). Developing intermediate triggers before declaring a PHEIC would mobilize the wider national and international community at earlier stages of a response without interfering with the criteria for a PHEIC that met the needs of the IHR (2005) (66).

Required actions

The United Nations must strengthen coordination mechanisms.



The Secretary General of the United Nations, with WHO and United Nations Office for the Coordination of Humanitarian Affairs, must strengthen coordination in different country, health and humanitarian emergency contexts, by ensuring clear United Nations systemwide roles and responsibilities; timely triggers to rapidly reset preparedness and response strategies during health emergencies; and, enhancing United Nations system leadership for preparedness, including through routine simulation exercises. WHO should introduce an approach to mobilize the wider national, regional and international community at earlier stages of an outbreak prior to a declaration of an IHR (2005) Public Health Emergency of International Concern.

Progress indicator(s) by September 2020

- The Secretary-General of the United Nations, with the Director-General of WHO and Under-Secretary-General for Humanitarian Affairs, strengthens coordination and identifies clear roles and responsibilities and timely triggers for a coordinated United Nations systemwide response for health emergencies in different countries and different health and humanitarian emergency contexts.
- The United Nations (including WHO) conducts at least two systemwide training and simulation exercises, including one covering the deliberate release of a lethal respiratory pathogen.
- WHO develops intermediate triggers to mobilize national, international and multilateral action early in outbreaks, to complement the existing mechanisms for later and more advanced stages of an outbreak under the IHR (2005).
- The Secretary General of the United Nations convenes a high-level dialogue with health, security and foreign affairs officials to determine how the world can address the threat of a lethal respiratory pathogen pandemic, as well as managing preparedness for disease outbreaks in complex, insecure contexts.

Ultimate objectives:

There is no ambiguity or delay in the United Nations systemwide response to a global health emergency. There are clear rules, roles and responsibilities, along with a designated leader, empowered with the authority to coordinate across the system and experienced in leading a global response through regular simulations or actual events. WHO can rapidly mobilize countries and partners early in an outbreak or health emergency.

ABBREVIATIONS

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CEPI	Coalition for Epidemic Preparedness Innovations
CFE	WHO Contingency Fund for Emergencies
DRC	Democratic Republic of the Congo
Gavi Alliance	Global Alliance for Vaccines and Immunisation (earlier title)
GDP	Gross domestic product
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GHSA	Global Health Security Agenda
GPMB	Global Preparedness Monitoring Board
IDA	International Development Association (World Bank)
IDA19	19 th replenishment of the International Development Association Funding
IHR (2005)	International Health Regulations (2005)
IMF	International Monetary Fund
JEE	Joint External Evaluation
MERS	Middle East respiratory syndrome
NAM	United States National Academy of Medicine
NAPHS	National Action Plan for Health Security
NIAID	United States National Institute of Allergy and Infectious Diseases
OCHA	United Nations Office for the Coordination of Humanitarian Affairs
PEF	Pandemic Emergency Financing Facility
PHEIC	Public Health Emergency of International Concern
PIP	Pandemic Influenza Preparedness Framework.
R&D	Research and development
R&D Blueprint	WHO Research and Demonstration Blueprint
SARS	Severe acute respiratory syndrome
SDG	Sustainable Development Goal
SPAR	States Parties' annual reporting under the IHR (2005)
WHE	World Health Organization Health Emergencies Programme
WHO	World Health Organization

Coordination. The organization of different stakeholders to enable them to work together effectively, through synchronization and integration of activities, responsibilities, and command and control structures to ensure that the resources are used most efficiently in pursuit of the specified objectives. There can be three levels of coordination: among organizations, among functions, and within programs.

Epidemic. An increase, often sudden, in the number of cases of a disease above what is normally expected in that population in that area (e.g. Ebola virus disease in West Africa in 2014-2016).

Health Security. The activities required to minimize the danger and impact of acute public health events that endanger the collective health of populations living across geographical regions and international boundaries.

Nagoya Protocol. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity. The main components are: 1) the obligation to obtain the authorization of providing countries before using a biological resource from their areas under national jurisdiction territory; and 2) the obligation to share monetary or non-monetary benefits with providing countries. The Protocol establishes broad terms of a bilateral system, implemented differently in each country. It can involve a wide range of requirements, from the need to obtain a permit to access a biological resource to the need to pay royalties on profit generated from commercial products developed using these resources. This results in a complex patchwork of legislation, which could potentially be difficult to navigate at the time of a public health emergency.

Pandemic. An epidemic that has spread over several countries or continents, usually affecting a large number of people (e.g. H1N1 influenza in 2009).

PHEIC. Public Health Emergency of International Concern. A PHEIC is defined in the IHR (2005) as "an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response". This definition implies a situation that is serious, sudden, unusual or unexpected; that carries implications for public health beyond the affected State's national border; and may require immediate international action.

PIP Framework. The Pandemic Influenza Preparedness Framework is an international mechanism adopted in 2011 by WHO Member States. It aims to improve global pandemic influenza preparedness and response by encouraging the sharing of pandemic influenza viruses, building global preparedness capacities against pandemic influenza and securing more equitable access to vaccines and other medical countermeasures in advance of an influenza pandemic.

Preparedness. The ability (knowledge, capacities, and organizations systems) of governments, professional response organizations, communities and individuals to anticipate, detect and respond effectively to, and recover from, the impact of likely, imminent or current health emergencies, hazards, events or conditions. It means putting in place mechanisms which will allow national authorities, multilateral organizations, and relief organizations to be aware of risks and deploy staff and resources quickly once a crisis strikes.

Response. Includes immediate actions to save lives, protect property and meet basic human needs. Response also includes the execution of emergency operations plans.

MEMBERS OF THE GLOBAL PREPAREDNESS MONITORING BOARD

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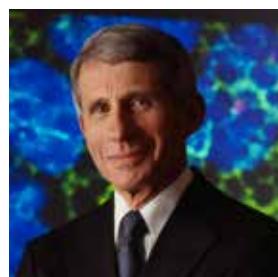
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EXHIBIT 459



Who We Are

PRESS RELEASE | **SEPTEMBER 10, 2018**

Global Preparedness Monitoring Board convenes for the first time in Geneva



GENEVA (10 September 2018) – The World Health Organization and the World Bank Group today convened the first meeting of the Global Preparedness Monitoring Board (GPMB), a new body set up to monitor the world's readiness to respond to outbreaks and other health emergencies.

The GPMB is chaired by Dr Gro Harlem Brundtland, former Prime Minister of Norway and former WHO Director-General and Mr Elhadj As Sy, Secretary General of the International Federation of Red Cross and Red Crescent Societies, and includes some of the most notable leaders in global health.

The GPMB has been established to monitor progress, identify gaps and advocate for sustained, effective work to ensure global preparedness. At its first meeting at WHO's headquarters in Geneva, the GPMB today discussed key issues in global preparedness and agreed its terms of reference and governance structure. The board aims to publish its first report on the global state of preparedness in September 2019.

"Despite all the progress we have made, the world remains vulnerable," said Dr Tedros Adhanom Ghebreyesus, WHO Director-General. "The Global Preparedness Monitoring Board brings together deep experience and expertise to help keep the world safe."

"There's no substitute for preparedness, and investing in it should be a top priority for the entire global community," said Dr Jim Yong Kim, President of the World Bank Group. "It is important that countries are beginning to take pandemic preparedness much more seriously."

The GPMB has its origins in the 2014 Ebola outbreak in West Africa, which devastated thousands of families, damaged economies and shook the world.

Since then, WHO has undergone major transformation, with the establishment of its health emergencies programme. In the Organization's new strategic 5-year plan, one of the three "triple billion" targets for 2023 is to see 1 billion people better protected from health emergencies.

The World Bank has also established the Pandemic Emergency Financing Facility and made its first cash disbursement to the Ebola outbreak in Democratic Republic of the Congo in May this year. As part of its IDA 18 commitment, the World Bank is supporting the development of pandemic preparedness plans in 25 low- and lower-middle income countries. It is also investing in preparedness in several countries in the East Asia and Pacific region, and in strengthening regional disease surveillance and monitoring capacity across East and West Africa.

Most importantly, countries and communities have embraced the need for preparedness, with WHO's Member States recommitting to establishing the capacities required under the International Health Regulations and dozens requesting Joint External Evaluations.

Contacts

<https://www.worldbank.org/en/news/press-release/2018/09/10/global-preparedness-monitoring-board-convenes-for-the-first-time-in-geneva>

EXHIBIT 460

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[DOCUMENTS & RESOURCES \(ANNUAL_REPORT.HTML\)](#)

BOARD

Co-chairs



The Board will monitor preparedness activities on a global scale, and will hold all actors, from private and public sectors, accountable for building essential public health capacities, generating sustainable financing and ensuring that necessary research and development is conducted.

Dr Gro Harlem Brundtland

[Read Bio ➔](#)

Pandemic preparedness must be as much local as global, and we must meaningfully engage local communities in preparedness, detection, response and recovery to disease outbreaks. We all need to be accountable to each other on the promises we make, and the results we achieve.

Mr Elhadj As Sy

Former Secretary General of the International Federation of
the Red Cross and Red Crescent Societies

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EXHIBIT 461

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The Event 201

Preprint · October 2019

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The Event 201

The Event 201 was a high-level pandemic exercise performed on October 18, 2019, in New York, NY. The exercise illustrated areas where public/private partnerships will be necessary during the response to a severe pandemic in order to diminish large-scale economic and societal consequences. Event 201 simulated an outbreak of a novel zoonotic coronavirus transmitted from bats to pigs to people that eventually becomes efficiently transmissible from person to person, leading to a severe pandemic.

The Johns Hopkins Center for Health Security in partnership with the **World Economic Forum** and the **Bill and Melinda Gates Foundation** hosted Event 201, a high-level pandemic exercise on October 18, 2019, in New York, NY.

The exercise illustrated areas where **public/private partnerships** will be necessary during the response to a severe pandemic in order to diminish large-scale economic and societal consequences.

Event 201 simulated an outbreak of a **novel zoonotic coronavirus transmitted from bats** to pigs to people that eventually becomes efficiently transmissible from person to person, leading to a severe pandemic.

The pathogen and the disease it causes were modeled largely on SARS, but it is

more transmissible in the community setting by people with mild symptoms.

There is no possibility of a vaccine being available in the first year.

There is a fictional antiviral drug that can help the sick but not significantly limit spread of the disease.

Since the whole human population is susceptible, during the initial months of the pandemic, the cumulative number of cases increases exponentially, doubling every week. And as the cases and deaths accumulate, the economic and societal consequences become increasingly severe.

Recommendations are:

1. Governments, international organizations, and businesses should plan now for how essential corporate capabilities will be utilized during a large-scale pandemic.
2. Industry, national governments, and international organizations should work together to enhance internationally held stockpiles of medical countermeasures to enable rapid and equitable distribution during a severe pandemic.
3. Countries, international organizations, and global transportation companies should work together to maintain travel and trade during severe pandemics. Travel and trade are essential to the global economy as well as to national and even local economies, and they should be maintained even in the face of a pandemic.
4. Governments should provide more resources and support for the development and surge manufacturing of vaccines, therapeutics, and diagnostics that will be needed during a severe pandemic.
5. Global business should recognize the economic burden of pandemics and fight for stronger preparedness.
6. International organizations should prioritize reducing economic impacts of epidemics and pandemics.
7. Governments and the private sector should assign a greater priority to developing methods to combat mis- and disinformation prior to the next pandemic response.

Among the selected “players” as they were called, was the **professor George Fu Gao**, who is director of the Chinese Center for Disease Control and Prevention since 2017. His specialization includes research on influenza virus interspecies transmission (host jump). He is also interested in virus ecology, especially the relationship between influenza virus and migratory birds or live poultry markets and the bat-derived virus ecology and molecular biology.

Prof. Gao was joined among others at the panel by the former Deputy Director of the CIA during the Obama term, **Avril Haines**. She also served as Obama’s Assistant to the President and Principal Deputy National Security Advisor.

Another of the players at the Gates event was **Rear Admiral Stephen C. Redd**, Director of the Office of Public Health Preparedness and Response at the Centers for Disease Control and Prevention (CDC).

Rounding out the group was **Adrian Thomas**, the Vice President of Johnson & Johnson, the giant medical and pharmaceutical company. Thomas is responsible for pandemic preparedness at J&J including developing vaccines for Ebola, Dengue Fever, and HIV.

And there was **Martin Knuchel**, Head of Crisis, Emergency & Business Continuity Management, for **Lufthansa Group Airlines**. Lufthansa has been one of the major airlines dramatically cutting flights during the COVID-19 pandemic crisis.

Bill Gates also made a 2019 Netflix video which made an imaginary scenario.

The video, part of the “Explained” series, imagined a wet market in China where live and dead animals are stacked and a highly deadly virus erupts that spreads globally.

VACCINES

Inovio Pharmaceuticals of Pennsylvania received \$9 million from the **Gates-backed CEPI, Coalition for Epidemic Preparedness Innovations**, to develop a vaccine, INO-4800, which is about to test on humans in April.

They plan on delivering one million doses by year-end 2020 with existing resources and capacity. INOVIO Pharmaceuticals, Inc. announced that it has received a new \$5 million grant from the Bill & Melinda Gates Foundation to accelerate the testing and scale-up of CELLECTRA® 3PSP proprietary smart device for the **intradermal delivery** of INO-4800, a DNA vaccine for COVID-19 disease.

Gates Foundation monies via CEPI are financing development of a new vaccine method known as **messenger-RNA**.

They are co-funding the **Cambridge, Massachusetts biotech company, Moderna Inc.**, to develop a vaccine against the Wuhan novel coronavirus, the SARS-CoV-2.

Moderna’s other partner is the US National Institute of Allergy and Infectious Diseases (NIAID), a part of the National Institutes of Health (NIH).

Moderna has announced the dosing of the first participant in a phase 1 study of mRNA-1273, the company's mRNA vaccine candidate against the novel coronavirus.

The phase 1 study will examine the safety and immunogenicity of three dose levels of mRNA-1273 (25, 100, 250 µg) to be given on a two-dose vaccination schedule, with a gap of 28 days.

The company intends to have 45 healthy adults in the early-stage trial, which will be followed through 12 months after the date of the second vaccination.

Another biotech company working with mRNA technology to develop a vaccine for the COVID-19 is a **German company, CureVac**. Since 2015 CureVac has received money from the Gates Foundation to develop its own mRNA technology.

The Gates Foundation and related entities such as CEPI constitute the largest funders of the WHO. Its current director, **Tedros Adhanom**, the first WHO director in history who is not a medical doctor, worked for years on HIV with the Gates Foundation. Tedros Adhanom is one of the leaders fighting the COVID-19 pandemic.

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EXHIBIT 462



EVENT 201 MODEL

Disclaimer: this model was used exclusively for the exercise in October 2019 and does not relate to and cannot be applied to the current 2019-nCoV outbreaks because the epidemiologic inputs in this model differ from what is observed in 2019-nCoV.

Prepared by Caitlin Rivers

Date: October 11, 2019

The Event 201 model simulates an outbreak of a moderately transmissible pathogen in a fully susceptible population. The model is intended to be a realistic representation of how a novel infectious disease could become a pandemic in the absence of adequate control measures.

Model Description

We used an ordinary differential equation approach to simulate the Event 201 pandemic. A graphical depiction of the model structure and a table of the key parameters are available in the Appendix. The model contains six compartments representing different stages of infection. Key features of the model include two compartments for individuals infectious in the community: half develop mild illness (I_M) and half develop severe illness (I_S). Patients with severe infection either die (D) or recover (R) at rate α . Those with a mild infection move to the recovered compartment at rate δ .

Global Spread

Following the initial spillover event in a large city in South America, 300 of the largest cities in the world were stochastically seeded with infectious cases to represent disease spread through international travel. The rate at which new cities were added to the model accelerates as time progresses, much like the growth of the epidemic itself. The number of imported cases ranged between 1 and 4 for each city.

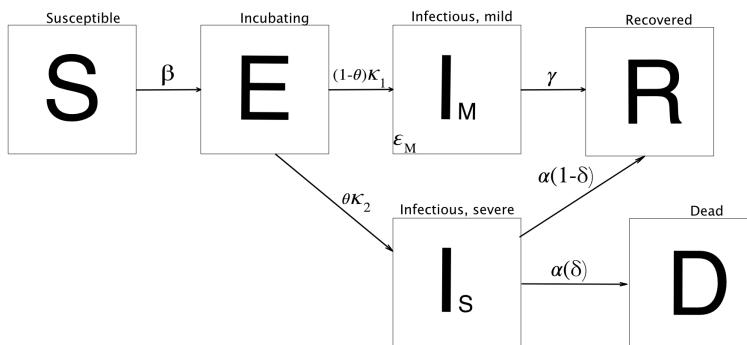


The model was run for each individual city in turn. To simulate the stochastic nature of outbreaks, parameters for each city were randomly selected from realistic distributions. The force of infection, β , was chosen from a normal distribution calibrated to produce an overall basic reproduction number of 1.7 (the reproduction number of individual cities ranged from 1.1 to 2.6). The case fatality risk (CFR) of hospitalized patients was chosen from a normal distribution with a mean of 14%, reflecting expected variation in the ability of healthcare systems to provide high quality care when faced with large numbers of critically ill patients. Patients with mild illness have a CFR of 0%, for an overall estimate of 7%.

The case counts reported in the exercise represent infections the severe compartment exclusively, under the assumption that mild illnesses in the community are less likely to be captured by surveillance systems. The exercise also reports only on the 300 global and 300 US cities represented in the model. For these reasons, the numbers reported in the scenario are conservative. However, like all models of this type, a core assumption is that the trajectory of the outbreak remains continuous. In real outbreaks, the trajectory is constantly changing in response to a number of factors like collective behavior change, which tend to slow outbreak growth.



Appendix: Key model parameters



β	transmission rate	variable	ϵ_M	reduced infectiousness	none
κ_1	incubation period, mild	5 days	θ	fraction severe	50%
κ_2	incubation period, severe	5 days	α	days to outcome in hospitalized	10 days
γ	days to recovery	7 days	δ	case fatality risk in hospitalized	variable - 14% on average

EXHIBIT 463



COMMUNICATION IN A PANDEMIC

Prepared by Marc Trotchoaud and Divya Hosangadi

Effective communication during public health events can be critical to public health response efforts. Public health messages help inform the public about risks and protective actions and, done correctly, are a critical component of community engagement and the buildup of public trust. Yet, true information about public health concerns is increasingly competing with false messages that can damage public confidence in health interventions and health authorities. These false messages are often defined as misinformation, erroneous information shared through various channels, and disinformation, purposefully spread false or misleading information. The information environment is increasingly made up of a mix of information coming from web sources and other media, in addition to historical sources such as print and TV news media. However, the influence of social media has made the spread of false information even more pernicious.

Over the past 15 years, there has been a global surge in the adoption of social media technologies. In 2019, 6 social media companies had more than 1 billion active monthly users.¹ Although originally designed for virtual engagement with personal networks, social media platforms have grown rapidly to share major roles in the economy and the transfer of information. According to the Pew Research Center, social media officially outpaced print newspaper as a source of news among the entire United States population.² Furthermore, across countries, regardless of a nation's socioeconomic status, younger populations rely even more heavily on social media as a news source.³

Disinformation campaigns are widely recognized in the political world but have been identified in the public health realm as well. In the fall of 2018, a team of researchers systematically identified a concerted effort to spread disinformation and discord about vaccine safety.⁴ Public health response efforts for the currently ongoing Ebola outbreak in the Democratic Republic of the Congo (DRC) have been challenged by disruptive rumors that have occasionally targeted public health responders.^{5,6} Misinformation during a public health emergency is a particularly concerning threat, because of the time-dependent nature of outbreak response and the corrosive effect misinformation can have on public trust. Current solutions to the spread of mis- and disinformation are limited. Social media platforms have attempted to change their algorithms to limit the spread of false



information and promote correct information, but the problem of misinformation continues.^{7,8} Many misinformation response actions have been developed to be used against political misinformation and disinformation but may be applied in response to an epidemic. More than 50 countries globally have taken different government-led actions that, in theory, aim to combat misinformation.⁹ These actions can range from media literacy campaigns and fact-checking websites to more extreme measures, such as jailing users for publishing content deemed to be misinformation. In some cases, authorities have shut down social media sites or the internet entirely.¹⁰⁻¹²

However, censoring social media content and denying a population access to the internet has serious consequences. In addition to ethical considerations, there is mounting evidence to suggest that there are serious economic consequences to shutting down the internet. According to the Indian Council for Research on International Economic relations, the estimated 16,000 hours of international internet shutdown in India resulted in around US\$3 billion in economic losses.¹²

Misinformation and disinformation are likely to be serious threats during a public health emergency. Unfortunately, thus far, there are limited ways to control the propagation of misinformation, leading to potentially draconian methods to manage this problem.

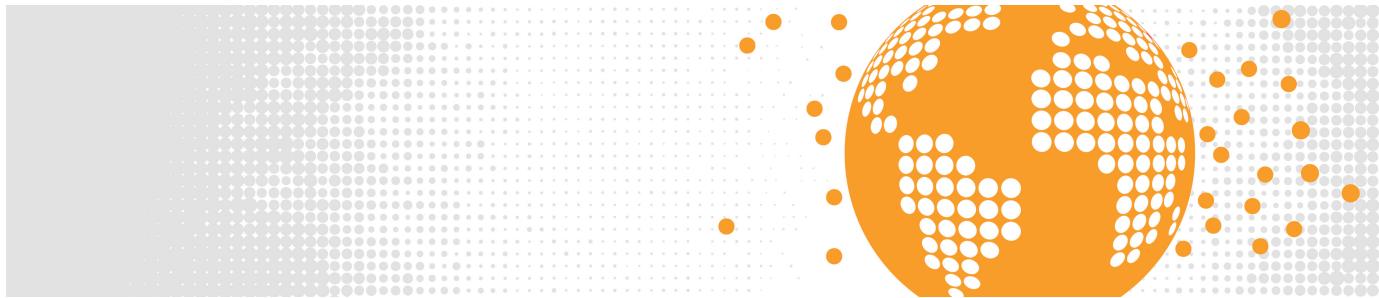
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EXHIBIT 464

[ABOUT](#)[PLAYERS](#)[VIDEOS](#)[RECOMMENDATIONS](#)[RESOURCES](#)[CONTACT](#)SEARCH [Event 201](#) > [scenario](#)

The Event 201 scenario

Event 201 simulates an outbreak of a novel zoonotic coronavirus transmitted from bats to pigs to people that eventually becomes efficiently transmissible from person to person, leading to a severe pandemic. The pathogen and the disease it causes are modeled largely on SARS, but it is more transmissible in the community setting by people with mild symptoms.

The disease starts in pig farms in Brazil, quietly and slowly at first, but then it starts to spread more rapidly in healthcare settings. When it starts to spread efficiently from person to person in the low-income, densely packed neighborhoods of some of the megacities in

Media

[Event 201 Media](#)[Videos](#)[Photos](#)[#Event201](#)

Case 2:20-cv-02470-WBS-JDP Document 14 Filed 12/29/20 Page 121 of 211
South America, the epidemic explodes. It is first exported by air travel to Portugal, the

United States, and China and then to many other countries. Although at first some countries are able to control it, it continues to spread and be reintroduced, and eventually no country can maintain control.

There is no possibility of a vaccine being available in the first year. There is a fictional antiviral drug that can help the sick but not significantly limit spread of the disease.

Since the whole human population is susceptible, during the initial months of the pandemic, the cumulative number of cases increases exponentially, doubling every week. And as the cases and deaths accumulate, the economic and societal consequences become increasingly severe.

The scenario ends at the 18-month point, with 65 million deaths. The pandemic is beginning to slow due to the decreasing number of susceptible people. The pandemic will continue at some rate until there is an effective vaccine or until 80-90 % of the global population has been exposed. From that point on, it is likely to be an endemic childhood disease.

EXHIBIT 465

NOVEMBER 2019

Ending the Cycle of Crisis and Complacency in U.S. Global Health Security

A Report of the CSIS Commission on Strengthening America's Health Security

CO-CHAIRS

Kelly Ayotte
Julie Gerberding

PROJECT DIRECTOR

J. Stephen Morrison



CSIS

CENTER FOR STRATEGIC &
INTERNATIONAL STUDIES



THE CSIS COMMISSION ON
Strengthening America's
Health Security

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Health Security

About CSIS

Established in Washington, D.C., over 50 years ago, the Center for Strategic and International Studies (CSIS) is a bipartisan, nonprofit policy research organization dedicated to providing strategic insights and policy solutions to help decisionmakers chart a course toward a better world.

In late 2015, Thomas J. Pritzker was named chairman of the CSIS Board of Trustees. Mr. Pritzker succeeded former U.S. senator Sam Nunn (D-GA), who chaired the CSIS Board of Trustees from 1999 to 2015. CSIS is led by John J. Hamre, who has served as president and chief executive officer since 2000.

Founded in 1962 by David M. Abshire and Admiral Arleigh Burke, CSIS is one of the world's preeminent international policy institutions focused on defense and security; regional study; and transnational challenges ranging from energy and trade to global development and economic integration. For the past eight years consecutively, CSIS has been named the world's number one think tank for defense and national security by the University of Pennsylvania's "Go To Think Tank Index."

The Center's over 220 full-time staff and large network of affiliated scholars conduct research and analysis and develop policy initiatives that look to the future and anticipate change. CSIS is regularly called upon by Congress, the executive branch, the media, and others to explain the day's events and offer recommendations to improve U.S. strategy.

CSIS does not take specific policy positions; accordingly, all views expressed herein should be understood to be solely those of the author(s).

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About the CSIS Commission on Strengthening America's Health Security

The CSIS Commission on Strengthening America's Health Security is a two-year effort organized by the CSIS Global Health Policy Center. The Commission brings together a distinguished and diverse group of high-level opinion leaders who bridge security and health, comprising six members of Congress, past administration officials, and representatives from industry, private foundations, universities, and nongovernmental organizations. The Commission is advised by a group of preeminent subject experts. The Commission's core aim is to chart a bold vision for the future of U.S. leadership in global health security — at home and abroad.

In recent years, U.S. senior policymakers have shown greater appreciation of the growing importance of health security to U.S. national interests and of the need for a stronger, more coherent, integrated, better resourced, and more reliably sustained U.S. doctrine for global health security. There is recognition that increasing levels of global disorder and conflict across the world are resulting in destruction of public health infrastructure and capacity, reduced access to critical services for vulnerable populations, and heightened risk of sudden outbreaks. These health threats undermine the economic and political security of nations.

While formidable obstacles remain, we are convinced there is a ripeness to health security, an opportunity to press for strengthening America's policy approaches in a way that can drive forward overall U.S. global health engagement, bring about new resources, and heighten the engagement of industry and security institutions, in partnership with other partner countries, multilateral institutions, and civil organizations.

The Commission is directed by J. Stephen Morrison, CSIS senior vice president and director of the Global Health Policy Center. The Commission's Secretariat is supported by Anna Carroll and Samantha Stroman. More information on the Commission can be found on its dedicated microsite at <https://healthsecurity.csis.org>.

Acknowledgments

The following report is the culmination of a year and half of work by the CSIS Commission on Strengthening America's Health Security, directed by J. Stephen Morrison, CSIS senior vice president and director of the Global Health Policy Center.

CSIS staff members Anna Carroll and Samantha Stroman were indispensable to the research and writing of this report, as well as overseeing the organization and execution of the Commission's many far-flung activities. They deserve enormous praise for the high quality that has resulted from their exceptional skill and commitment.

The Commission would like to extend a special thanks to the team that laid the groundwork for and launched the Commission, including Chris Millard of the CSIS Global Health Policy Center and Rebecca Hersman, Sarah Minot, and Alice Hunt Friend of the CSIS International Security Program. The Commission would also like to thank Emily Foecke Munden for her extraordinary commitment in supporting and advancing the work of the Commission during its first year.

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The Commission would not be possible without the generous support of the Bill & Melinda Gates Foundation. That support takes many forms, for which the Commission is deeply grateful.

DISCLAIMER

The Commissioners participated in their individual capacity, not as representatives of their respective organizations. This report represents a majority consensus; no member is expected to endorse every single point contained in the document. In becoming a signatory to the report, Commissioners affirm their broad agreement with its findings and recommendations. Language included in this report does not imply institutional endorsement by the organizations that Commissioners represent.

Letter from the Co-Chairs

Over the course of our careers, we have witnessed, often up close, a mounting number of severe health security incidents, including the 2001 anthrax attacks, SARS in 2003, and the recurrent, dangerous outbreaks of influenza and Ebola, to name but the most conspicuous. Not only did these moments demonstrate the staggering public health, economic, and political costs borne of infectious disease outbreaks and biological attacks, they have convinced us that the United States needs a far better line of defense.

Since our time serving in the U.S. government, there has been a decisive shift in U.S. policy circles—one that we each welcome and wholeheartedly embrace. Today, there is a broad consensus that health security is national security, in a world that has become more dangerous, and where the most dangerous zones are in fact where outbreaks are often arising. There is recognition that increasing levels of global disorder and conflict around the world are resulting in the destruction of public health infrastructure and capacity, reduced access to critical services for vulnerable populations, and heightened risk of sudden outbreaks. There is greater awareness of emerging and re-emerging infectious disease epidemics, the rapid spread of drug-resistant pathogens, and the risk of unregulated advances in biotechnology. A growing number of policymakers now appreciate how health security risks undermine the social, economic, and political security of nations.

Now is the time for greater U.S. leadership and action in global health security. In 2017, CSIS President and CEO John J. Hamre invited us to chair a Commission that would chart a bold vision for the future of U.S. leadership in global health security—at home and abroad. The CSIS Commission for Strengthening America’s Health Security brought together a distinguished and diverse group of high-level opinion leaders who bridge security and health, comprising six members of Congress, past administration officials, and representatives

from industry, private foundations, universities, and nongovernmental organizations (NGOs).

This Commission has convened experts from across sectors and disciplines to shed light on the convergence and intensification of global health security threats we face today and to inform policy options for the U.S. government to address these threats more adeptly and cost effectively. Since its public launch in April 2017, the Commission met three times, held seven public events, published 15 policy briefs and commentaries, and convened 20 working group and roundtable discussions.

To an exceptional degree, each Commissioner actively contributed substantial time and effort to these events and publications. The Commission’s impressive productivity is a testament to the Commissioners’ belief in the importance of global health security issues, the power of U.S. leadership, and their conviction that we must do better.

This report is the culmination of our nearly two-year effort, a genuine consensus document. The report advances a doctrine of continuous prevention, protection, and resilience in the face of a growing number and variety of health security threats—naturally occurring, accidental, and deliberate.

The report focuses on a strategic set of recommendations that are timely, impactful, and compelling and that will result in greater efficiencies in the use of scarce resources. It calls for White House leadership; adequate, sustained, and rapid financing of pandemic preparedness and response; strengthened capacities to operate in a disordered world; and heightened attention to technological challenges. We urge the Congress and the administration to take action on these critical fronts and chart a united, bipartisan path toward strengthened global health security.

Co-Chairs

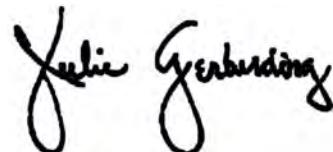
Kelly Ayotte

Former Senator (R-NH)



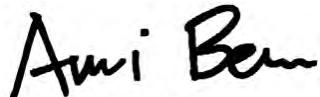
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Members of the CSIS Commission on Strengthening America's Health Security

U.S. Congressman Ami Bera
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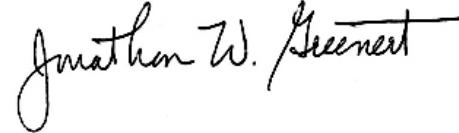
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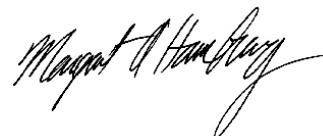
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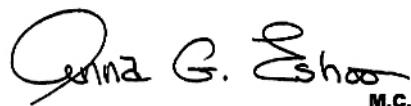
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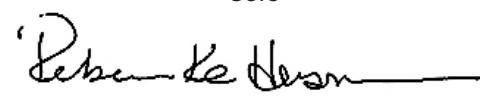
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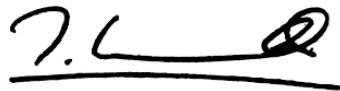
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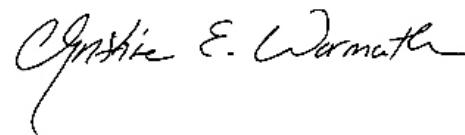
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Executive Summary

When health crises strike—measles, MERS, Zika, dengue, Ebola, pandemic flu—and the American people grow alarmed, the U.S. government springs into action.

But all too often, when the crisis fades and fear subsides, urgency morphs into complacency. Investments dry up, attention shifts, and a false sense of security takes hold.

In reality, the American people are far from safe. To the contrary, the United States remains woefully ill-prepared to respond to global health security threats. This kind of vulnerability should not be acceptable to anyone. At the extreme, it is a matter of life and death.

The CSIS Commission on Strengthening America’s Health Security urges the U.S. government to replace the cycle of crisis and complacency that has long plagued health security preparedness with a doctrine of continuous prevention, protection, and resilience. Such a strategic approach can restore U.S. leadership, strengthen financing and the speed of response, foster resilient health systems abroad, enhance the U.S. government’s ability to operate in disordered settings, and accelerate select technological innovations to secure the future. It will only be successful, however, if backed by sufficient political will, skilled execution, and a sustained commitment to accountability and efficiency in the use of scarce resources.

The United States faces heightened danger in an increasingly interconnected world. As the global population presses towards 9.7 billion by 2050 and expands into wild frontiers, as agriculture becomes more intensive, as cities of greater density and scale proliferate, and as the earth grows hotter, the threat of new emerging infectious diseases rises steeply.¹ Outbreaks proliferate that can spread swiftly across the globe and become pandemics, disrupting supply chains, trade, transport, and ultimately entire societies and economies.

At the same time, dangerous insecurity and conflicts are proliferating throughout the world, especially in those very places where outbreaks occur.

The business case to invest early in preparedness is crystal clear—and powerful. The United States must either pay now and gain protection and security or wait for the next epidemic and pay a much greater price in human and economic costs. The long-term costs of strategic protection and prevention programs are but a tiny fraction of the

astronomic costs of episodic, often chaotic responses to sudden, emergent crises. Investing strategically now is smart and cost-effective, brings proven results, and would draw support from across the political spectrum.

The Commission urges Congress and the administration to adopt the following integrated package of critical actions:

1. Restore health security leadership at the White House National Security Council.

Health security is national security. Strong, coherent, senior-level leadership at the National Security Council (NSC) is essential to guarantee effective oversight of global health security and biodefense policy and spending, speed and rigor in decisionmaking, and reliable White House engagement and coordination when dangerous pandemics inevitably strike. Leadership on the NSC can bring about key, targeted new investments while achieving much-needed reform of fragmented programs and higher efficiencies in the use of scarce resources.

2. Commit to full and sustained multi-year funding for the Global Health Security Agenda to build partner capacity.

U.S. direct investments remain essential to build health system capacity. The U.S. government can best protect the American people by stopping outbreaks at their source. The Global Health Security Agenda (GHSA) has a proven track record in building health security preparedness in low- and middle-income countries through new innovative partnerships with national governments, the private sector, and civil society groups. It is common sense for the United States to continue to support that successful agenda, not disrupt it.

3. Establish a Pandemic Preparedness Challenge at the World Bank to incentivize countries to invest in their own preparedness.

U.S. multilateral leadership is necessary to address the financing gap for preparedness, one of the starker problems in health security. Congress should press for U.S. leadership to launch a challenge initiative at the World Bank that will incentivize long-term investment by fragile and conflict-affected countries in their own basic health security capacities. Such country ownership is the ultimate and only sustainable solution to the finance gap.

4. Ensure rapid access to resources for health emergencies.

Stopping a global health security crisis requires swift and early action, backed by quick-disbursing resources. Congress should increase contingency fund levels for the U.S. Centers for Disease Control and Prevention’s (CDC) Infectious Diseases Rapid Response Reserve Fund and the U.S. Agency for International Development’s (USAID) Emergency Reserve Fund for infectious disease outbreaks. The U.S. government should also make annual contributions to the World Health Organization (WHO) Contingency Fund for Emergencies (CFE).

5. Establish a U.S. Global Health Crises Response Corps.

Small teams of select, highly experienced U.S. civilian public health and humanitarian experts, working alongside local partners and national leaders, form the “cerebral cortex” of outbreak response. Their combined presence can be a high-impact game changer. As seen in the Democratic Republic of the Congo (DRC), when U.S. and other critically important experts are barred from outbreak zones due to insecurity, the implications are grave. The world has grown more dangerous, and the danger zones are precisely where the greatest health security risks frequently reside. Risk aversion has impeded USAID and CDC deployments into several outbreak zones besides the DRC: South Sudan, Iraq, Syria, and Nigeria. Additionally, Yemen and Afghanistan offer minimal access. Caution among policymakers has understandably increased in response to this trend, brought vividly to the fore by tragedies such as the fatal attacks upon U.S. personnel in Benghazi, Libya, in 2012. But the United States simply cannot afford to remain on the sidelines of rapidly emerging health crises. A U.S. Global Health Crises Response Corps answers today’s stark new realities. It will build systematically upon—not duplicate—existing rapid response capabilities at the CDC and USAID.

6. Strengthen the delivery of critical health services in disordered settings.

The proliferation of chronic and emerging conflicts, humanitarian crises, and fragile and disordered states places an immense strain on already weak health systems, jeopardizing outbreak response. This problem has moved to center stage in U.S. global health security policy. The U.S. government should strengthen and adapt programs and capacities to deliver health services in fragile and conflicted settings that meet the special needs of acutely vulnerable popula-

tions, especially women and children. The U.S. government should prioritize the continuity of immunization systems, strengthening the protection against—and response to—gender-based violence (GBV), and strengthening the delivery of maternal and reproductive health and family planning assistance.

7. Systematically confront two urgent technology challenges: the need for new vaccines and therapeutics and the public health communications crisis.

There is a race underway to develop new vaccines, therapeutics, and diagnostics in light of the mounting risks of emerging infectious diseases and growing resistance. It is essential to plan strategically, with strong private-sector partners, to support targeted investments that will accelerate the development of new technologies for epidemic preparedness and response. The U.S. government should invest directly in the Coalition for Epidemic Preparedness Innovations (CEPI). There should be a heightened focus on the development of a universal flu vaccine and new antibiotics. These tools should be developed in safe and secure ways that maximize societal benefit while minimizing the potential for misuse. Across programmatic and disease areas, it should be a U.S. policy priority to adopt and integrate digital tools to improve the quality and use of data.

An unforeseen, historic communications crisis in public health is unfolding, at home and abroad. Fueled by social media, ideology, societal discontent, and the rise of online networks of anti-vaccination activists, there has been a sharp decline in popular trust in science, public health authorities, and industry. When disinformation crowds out facts, confidence can erode precipitously, and control of diseases such as measles and polio can regress. Sudden unforeseen “digital wildfires,” often at moments of crisis, can derail outbreak responses. Congress should press for the U.S. government to expand its efforts to better understand this complex phenomenon, effectively communicate accurate science, restore trust and confidence, and reclaim social media as a force for good in public and global health. Knowledge and expertise outside public health will be essential in this effort: in media technology, cybersecurity, legal and regulatory regimens, communications, culture, and sociology. Innovative digital tools will lie at the center of concrete solutions.

SUMMARY OF RECOMMENDED FUNDING		
Recommendation	Programs and Initiatives	Proposed Increase Over Current Level <i>*Figures Presented in Millions USD^A</i>
1. Restore health security leadership at the White House National Security Council.	N/A	N/A
2. Commit to full and sustained multi-year funding for the Global Health Security Agenda to build partner capacity.	USAID	\$35
	CDC	\$100
3. Establish a Pandemic Preparedness Challenge at the World Bank to incentivize countries to invest in their own preparedness.	Pandemic Preparedness Challenge	\$30
4. Ensure rapid access to resources for health emergencies.	CDC Infectious Diseases Rapid Response Reserve Fund	\$200 ^B
	USAID Emergency Reserve Fund	\$248
	WHO Contingency Fund for Emergencies	\$25
5. Establish a U.S. Global Health Crises Response Corps.	Global Health Crises Response Corps	\$50
	CDC Support to National Partners	\$36
6. Strengthen the delivery of critical health services in disordered settings.	Immunizations	\$6
	Women and Girls	\$30
7. Systematically confront two urgent technology challenges: the need for new vaccines and therapeutics and the public health communications crisis.	Coalition for Epidemic Preparedness Innovations	\$40
	Universal Flu Vaccine	\$60
	Vaccine Confidence	\$25
	Biosafety	\$10
	Biosecurity	\$10
TOTAL:		\$905

A. Recommended funding amounts include both annual investments and one-time investments. For further detail, please see Appendix I: Illustrative Costing for Recommended Programs and Initiatives.

B. It is proposed that the CDC Infectious Diseases Rapid Response Reserve Fund and the USAID Emergency Reserve Fund be set and maintained at a level of \$250 million each, replenished on an annual basis as warranted.

A World of Peril

We live in a world of heightened microbial danger. Infectious disease outbreaks are far more frequent, far more extreme, and impose far higher costs.²

An Ebola outbreak in eastern Democratic Republic of the Congo (DRC), the tenth such outbreak in the country since the virus was discovered there in 1976, has continued to simmer since August 2018 and threatens both global health and global security.³ The international response has been gravely impeded by armed conflict and community resistance within the complex political and security context of eastern DRC. The World Health Organization (WHO) declared the outbreak a Public Health Emergency of International Concern (PHEIC) on July 17, 2019, almost one year after the outbreak was announced.^{4,5} As of October 2019, the outbreak has not been brought under control, and the future remains highly uncertain.

More than 3,200 cases have been confirmed, and over 2,100 people have died as of early October 2019.⁵ There

have been confirmed cases in Uganda and suspected cases in Tanzania.^{6,7} Cases have also appeared in Goma, a populous transit hub on the Congolese border with Rwanda, the most densely populated country in Africa.⁸ In this fragile context, the DRC is simultaneously experiencing concurrent outbreaks of vaccine-derived poliovirus, measles, and cholera.^{9,10}

The situation in the DRC is emblematic of widening global disorder, comprised of chronic and emerging conflicts, humanitarian crises, fragile states, countries prone to repression and gross malgovernance, and stateless corners of the world. This disorder is not abating, and it has deep health security and national security implications for the United States. Increasing numbers of infectious disease outbreaks occur in these contexts, along with increasing attacks upon vital health infrastructure and increased displacement of vulnerable populations, interrupting access to critical health services. Disease and disorder fuel one another, as terrorist groups and violent extremist ideologies stoke health crises and mass migration by attacking vaccinators and other health workers from Pakistan to Syria, Yemen, Somalia, Afghanistan, and elsewhere.¹¹

A. Refer to Appendix III: Glossary of Key Terms for more information on the PHEIC and other key terms and programs cited in this paper.

Health workers perform medical checkups on a new, unconfirmed Ebola patient inside a newly built Ebola treatment centre on November 7, 2018 in Bunia, Democratic Republic of the Congo.

JOHN WESSELS/AFP VIA GETTY IMAGES





"The breakdown of health and other social services in disordered settings can easily be exploited and exacerbated by terrorist groups and violent extremists. By addressing the health needs of vulnerable populations in crisis zones, we can help to strengthen community resilience, defend against terrorist exploitation, and inoculate against violent radicalization."

— Juan Zarate, CSIS and Financial Integrity Network

THE DISORDERED WORLD

The disordered world spans chronic and emerging conflicts, humanitarian crises, fragile states, places with gross malgovernance, and stateless spaces.¹² Chronic wars and unstable and fragile states have proliferated in recent years. The number of major violent conflicts has tripled since 2010, and the average duration of civil wars in progress has increased to more than 20 years.^{13,14} From 2005 to 2017, the number of active crises receiving an internationally-led response almost doubled, jumping from 16 to 30.¹⁵ This proliferation of insecurity and fragility has fueled the highest levels of displacement on record. More than 68.5 million people were forcibly displaced worldwide as of June 2018, compared to 33.9 million in 1997.

The disordered world is evolving swiftly and is generating new, destabilizing health security threats. Access to basic health services degrades significantly as security is reduced and populations are displaced. A persistent state of crisis, violence, and instability leads to the flight of indigenous health care providers and the collapse of health infrastructure. This is accelerated by the deliberate targeting of health care providers and other humanitarian actors.¹⁶

Current global health infrastructure is largely built on national governments and government health systems, but the disordered world is defined by the weakness or absence of effective partner governments willing or able to participate in international cooperation for health security. At the same time, the rise of populist

nationalism around the world is disrupting the liberal international order and challenging traditional models of global health.

This is our new reality, and there are no quick fixes. While some actors have already begun to adapt, the challenges of the disordered world demand a more significant shift in how we operate. The recommendations proposed in this report reflect this new reality.

Today, disorder is fueling geopolitically volatile health security crises not only in the DRC but also in Syria, Yemen, Afghanistan, Pakistan, and Venezuela. The world has become more dangerous, precisely where many acute health security threats reside. This stark reality exposes several serious challenges: how are U.S. and other essential civilian public health and humanitarian experts to deploy safely into these austere environments in order to partner with local officials to detect and arrest highly dangerous outbreaks? How can the U.S. government and its partners meet the acute health and protection needs of the most vulnerable populations, in particular women and girls? And how can the U.S. government and its partners protect immunization and other critical health infrastructure prone to damage and disruption?

Seasoned U.S. civilian personnel with essential expertise from the U.S. Agency for International Development (USAID) and the U.S. Centers for Disease Control and Prevention (CDC) initially deployed to the most acutely affected areas of eastern DRC in August 2018, soon after the Ebola outbreak was declared. They were quickly

withdrawn after significant security incidents and have not been permitted to return since.¹⁷ The absence of small teams of highly skilled U.S. experts from the hot zones, where they normally would join with local and international partners to provide invaluable guidance, has proven enormously costly in eastern DRC. CDC and USAID teams have experienced similar blockages to deployment on security grounds in South Sudan, Iraq, Syria, and Nigeria. Access to Yemen and Afghanistan remains starkly minimal. The CSIS Task Force on Humanitarian Access has explored the impact of intensifying blocked humanitarian access—including roadblocks or attacks on aid workers, bureaucratic constraints, and donor regulations—all of which limit the ability of humanitarian actors to reach the most vulnerable.¹⁸

In the coming years, the United States and its partners can expect to see repeated instances of blocked access to serious outbreaks in insecure settings. That challenge begs for a solution, namely, a dedicated commitment to prudently manage—not prohibit—such lifesaving deployments of U.S. experts.

A second peril is the threat of losing altogether an essential disease-fighting tool, antibiotics. Antimicrobial resistance (AMR) is a complex, long-range global crisis menacing the foundations on which modern medicine is built. The problem lies not just in the lack of new antibiotics; it encompasses their gross misuse in human and animal health. Drug-resistant infections now cause 700,000 deaths per year, with 230,000 of those deaths from drug-resistant tuberculosis alone.¹⁹ Without action, annual deaths from resistant infections could rise to 10 million people per year by 2050 and cause an economic crisis

similar in scale to the 2008 Great Recession.²⁰

New, better vaccines and antibiotics are one essential answer to the expansion of resistance, along with strategic planning, better microbial stewardship, more careful antibiotic use, and better basic health systems. Vaccines and antibiotics have revolutionized infectious disease prevention and treatment, saved millions of lives worldwide, and advanced economic stability and growth. Yet their discovery and development increasingly occur in a deeply problematic and urgent context, characterized by market failures and uncertain economic and budgetary environments.

Advances in biotechnology may foster the development of these new vaccines and therapeutics, but they also pose an additional risk. As scientists develop and apply new biotechnologies, they may increase the transmissibility and pathogenicity of naturally occurring microbes. With these changes come greater biosafety and biosecurity concerns and the rising possibility of accidental or intentional exposure of people, animals, or the environment to dangerous, novel microbes, and even the initiation of a global pandemic.

A third swiftly evolving peril is vaccine hesitancy and the power of weaponized social media. In 2019, the WHO recognized for the first time the recent, steep decline of public trust and confidence in vaccines as among the top 10 global health challenges.²¹ That striking judgment reflects a broader phenomenon: the rise of sophisticated anti-vaccine online networks and the growing mistrust of science, public health authorities, the private sector, and government, fueled by the rapid, deliberate spread of disinforma-



"The systems that have been built to combat specific diseases provide the foundation to build a strong and resilient system for health that can prevent, detect, and respond to current and new health threats. It is important that the U.S. government continue to work to manage and control endemic infectious diseases, such as tuberculosis, malaria, and HIV."

— Ambassador Mark Dybul, Georgetown University Medical Center



tion, including conspiracy theories on social media and other digital platforms. Insular ethnic and religious communities are especially vulnerable, as are young parents.

Trust and confidence in vaccines can rapidly collapse, as has already occurred across many diverse settings, often among anxious parents who face a confusing array of information as they seek to make the best choices for their children.²² Concurrently, vaccine advocates find themselves targeted and intimidated by the adversaries of vaccines.

Vaccine hesitancy has contributed to a regression in immunization coverage across a number of disease areas, including polio, cervical cancer, and measles. It strikes at home and abroad, in rich and poor countries alike. In 2000, measles was declared eliminated from the United States. As of August 2019, more than 1,200 cases had been identified in 30 U.S. states, the highest case count in 25 years.²³ Massive measles outbreaks are also unfolding in Ukraine, Israel, the Philippines, Madagascar, and elsewhere. Europe had nearly 83,000 cases in 2018, an

astonishing number.²⁴ The DRC has had around 115,000 cases as of July 2019.²⁵

While vaccine hesitancy is fundamentally a public health problem, the solutions and the skill sets required to understand this complex phenomenon and rebuild confidence and trust lie, in part, outside the discipline of public health: in communications and messaging; legal and regulatory measures; opinion tracking; intelligence; knowledge of local networks, trust building, and other focal areas for anthropological study; and cyber security and the understanding of social media technology.

Bad Habits, Barriers, and Vulnerabilities

Confronting twenty-first century health security threats demands a continuous, strategic response.

Yet the United States has long been mired in a cycle of crisis and complacency—resulting in ad hoc, stop-go approaches and a short-sighted dependence on emergency interim funding which inevitably sputters to its end, returning us to a state of vulnerability.

Over several successive administrations, the White House has seldom exercised sufficiently authoritative, high-level leadership, creating acute threats to U.S. national interests when dangerous outbreaks occur at home and abroad. U.S. programs on global health security are fragmented, scattered across diverse executive agencies, and not clearly prioritized. The weakness of White House leadership has left unanswered the persistent question of how to streamline programs, eliminate redundancies, and achieve higher efficiencies in the use of scarce resources.

Too often, the U.S. government has succumbed to complacency, failing to recognize the value of investing in preparedness and the huge costs of inaction, only to pay a steep price later. Having not sufficiently invested in health systems and preparedness in West Africa, the U.S. government expended nearly \$2.4 billion (roughly half of the total international investment) to support the Liberian, Sierra Leonean, and Guinean efforts to arrest the 2014-2016 Ebola outbreak.²⁶ A recent study estimates the social and economic burden of the West Africa outbreak ultimately totaled more than \$53 billion, at an average of more than \$1.8 million per Ebola case.²⁷ Other recent outbreaks proved even more costly. The MERS outbreak in South Korea in 2015, a mere 186 cases, cost South Korea \$10-13 billion—more than \$50 million per case.²⁸

Unforeseen biological threats can be intrinsically confusing and can require responses from multiple U.S. agencies. It is often difficult to categorize an emerging health threat definitively as a natural event, a lab accident, or a malevolent act. Outbreaks may involve pathogens the world has not seen before, emerging in unexpected places and geographies, involving heretofore unknown actors.



Cost the economies of southeast Asia **between \$40-45 billion.**

That is equivalent to about \$5 million per case.



Cost the global economy **over \$53 billion.**

That is equivalent to more than \$1.8 million per case.



Cost South Korea **between \$10-13 billion.**

That is equivalent to more than \$50 million per case.



"Today we are facing the threat of a pandemic that could kill up to 80 million people and wipe out five percent of the global economy. The Global Preparedness Monitoring Board is doing critical work in partnership with the World Health Organization and the World Bank to ensure that more countries are prepared for global health crises."

— Trevor Mundel, Bill & Melinda Gates Foundation

THE WORLD IS UNPREPARED

Two recent reports underscore the lack of pandemic preparedness across the globe and ponder the question of what more needs to happen now. The Global Preparedness Monitoring Board (GPMB) was co-established by the WHO and the World Bank in the aftermath of the 2014-2016 West Africa Ebola crisis. The GPMB is an independent body tasked with monitoring preparedness for global health crises.²⁹ It has the promise to become an authoritative, credible global oversight mechanism. In September 2019, the GPMB released its first annual report, *A World at Risk*, providing a "snapshot" of the international community's ability to prevent, detect, and respond to a global health threat.³⁰ The findings of the GPMB were unequivocal: the threat is growing, and the world is not prepared.

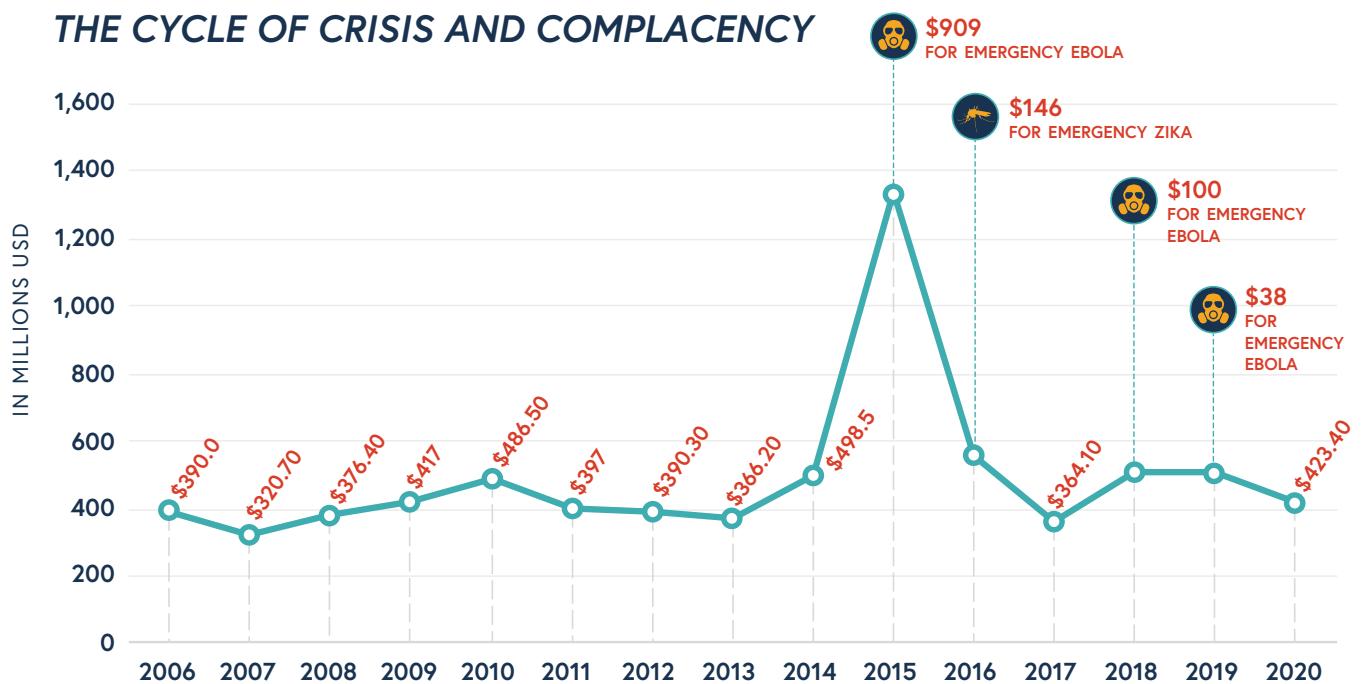
In October 2019, the Global Health Security Index reaffirmed the GPMB's findings. The Global Health Security Index is the first comprehensive assessment and benchmarking of health security and related capabilities across all 195 countries that make up the states parties to the International Health Regulations (IHR 2005).³¹ The Index is unprecedented in its comprehensiveness and granularity, drawing from volumes of open-source information and the input of hundreds of scientists and public health experts. The Index proved that it is possible to design and implement a rigorous methodology to systematically measure pandemic preparedness. The Global Health Security Index candidly and soberly found that no country is fully

prepared for epidemics or pandemics, concluding that collectively, international preparedness is weak. The average overall Global Health Security Index score among all 195 countries assessed was 40.2 of a possible score of 100.³²

The GPMB report and the Global Health Security Index each appeal to heads of state and international leaders to acknowledge the enduring, stark risks posed by global health insecurity and to heighten their engagement on a sustained basis. Both reports appeal to governments, from low-income to the most advanced economies, to invest more of their own resources in preparedness.³³ The CSIS Commission on Strengthening America's Health Security applauds these efforts, which align closely with the Commission's own findings and recommendations.

Preparedness can be a tough sell. It is asking governments to invest in things that are difficult to see. The goal of preparedness is to prevent bad things from happening, which means that success is rarely flashy but more often happens quietly and out of view.

The overwhelming responsibility to lead lies with the U.S. government and its partner governments. While the private sector, foundations, and international organizations are all essential to long-term health security solutions, they cannot be relied upon to lead. In the case of the AMR crisis, for example, it is inadvisable to assume the biopharmaceutical industry will devise solutions on its own. The number of companies conducting antibiotic research and development is declining, a reflection of complex scientific, regulatory, and market challenges. The U.S. government needs to



SOURCE: Kaiser Family Foundation, "Global Health Security Funding," accessed October 2019, <https://www.kff.org/interactive/budget-tracker/summary/Filer-Program-Area/Global-Health-Security/Agency/?view=range-years&startYear=2006&endYear=2020>.

provide more incentives and better answers as to how to reverse this trend and preemptively tackle this health security threat.

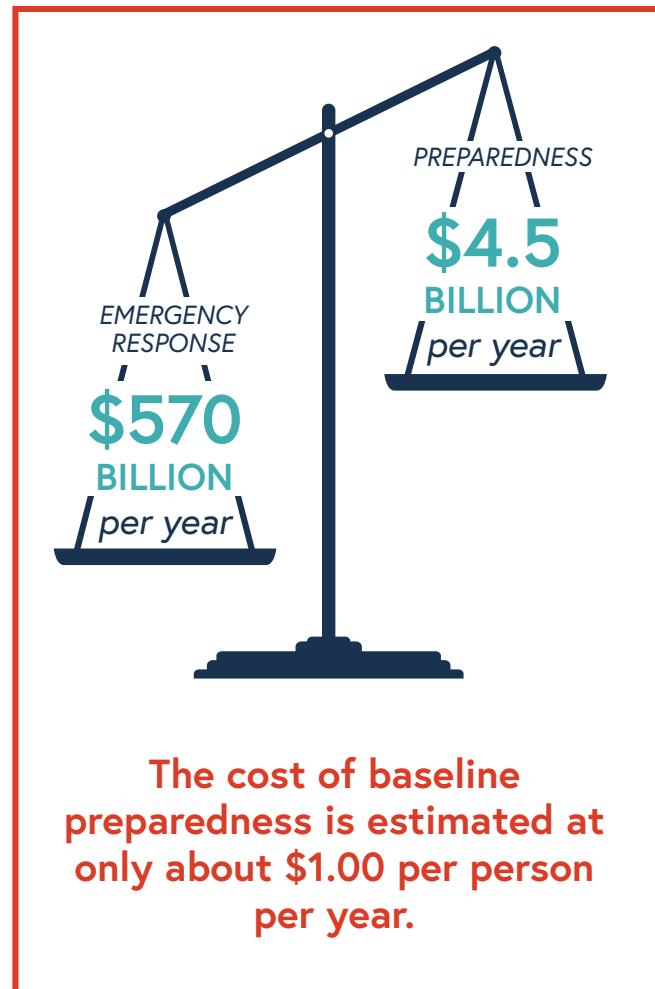
The countries that are the most vulnerable are not yet making the investments needed, even after conducting careful assessments and preparing national plans.³⁴ For many cash-strapped governments, budget commitments in health security compete against other worthy, politically sensitive, and very concrete priorities, including defense, education, and infrastructure. That financing gap is among the gravest challenges in health security. Chronic underinvestment has hindered genuine capacity building by low- and middle-income countries. This creates considerable innate risk of runaway outbreaks that may not be very visible at the outset but can quickly threaten U.S. national security interests as they spread. The U.S. government should develop programs which incentivize investment by the most vulnerable nations themselves.

A Moment to Change Course

Despite the barriers, new opportunities are arising.

As health security incidents occur more frequently and with higher visibility, velocity, and costs, leaders in the public, private, international, and social sectors (including philanthropies, NGOs, and academic institutions) have begun to take notice and think anew about what long-term strategy is required. Today, economists across sectors increasingly acknowledge the overwhelming business case for investment in health security. An exercise conducted in the aftermath of the 2014-2016 West Africa Ebola crisis calculated the inclusive costs of a severe influenza pandemic could be as high as \$80 billion in annual economic losses and \$490 billion in annual costs tied to illnesses and premature deaths, for a total of \$570 billion per year.³⁵ In contrast, a landmark study published by the National Academies of Sciences, Engineering, and Medicine determined that the cost of investing in basic health security is a relatively modest \$4.5 billion per year.³⁶ There is increasing understanding that the United States can afford to invest—and simply cannot afford not to invest in preventative strategies.

The cost of baseline preparedness is estimated at only about a dollar per person per year—and building and sustaining preparedness need not be an open-ended donor commitment.³⁷ Countries are capable of transitioning to self-reliance with the correct incentives and support. Low- and middle-income partner countries such as Vietnam, Uganda, Cameroon, Ethiopia, and Cambodia have already demonstrated their willingness to step forward, embrace independent assessments of their health security preparedness, develop national action plans, and join in capacity-building collaborations. The



WHO has been central to this effort and has made significant reforms to improve its own outbreak and emergency capacity and its ability to work with key partners.

In the United States, a stable bipartisan Congressional consensus has emerged in which health security has been



"When it comes to investing in America's global health security, an ounce of prevention is a pound of cure. Modest, sustained investment in public health preparedness each year is more effective and less expensive than paying enormous sums to respond and recover from a dangerous, major outbreak."

— Christine Wormuth, RAND Corporation



"I am proud to have forged bipartisan leadership in Congress on global health security issues. People across the country expect the federal government to be prepared to keep them safe during times of natural disasters or biological, chemical, radiological or nuclear threats to our public health and national security. Unfortunately, we remain largely reactionary in our response to pandemics and biological threats. Proactive efforts are critical to our national and health security. Bringing policymakers together to discuss these critical issues as well as the Commission's final recommendations are an essential element of advancing a coherent vision for U.S. global health security policy."

— U.S. Congresswoman Susan Brooks (R-IN-5)

largely insulated from political polarization. Though several committees and sub-committees have jurisdiction and funding authorities in this area, it has been possible to forge a unified vision of core goals and principles around pressing health security challenges.³⁸

B. Refer to Appendix II: Congressional Authorities and Oversight of U.S. Government Efforts to Advance Global Health Security for more information on relevant committees and subcommittees.

RECENT U.S. CONGRESSIONAL ACTION

There is strong bipartisan support in the U.S. Congress for global health security, as evidenced by the recent introduction of a number of bills in this area. Included below are highlights of recent proposed legislation related to global health security, although this is by no means an exhaustive list. The Commission is encouraged by and supportive of these efforts. They provide a foundation for sustained action by the U.S. Congress to strengthen global health security.

DEVELOPING AN INNOVATIVE STRATEGY FOR

ANTIMICROBIAL RESISTANT MICROORGANISMS

(DISARM) ACT OF 2019: In June 2019, Senators Johnny Isakson (R-GA) and Bob Casey (D-PA) introduced the DISARM Act.³⁸ This proposal seeks to strengthen the research and development pipeline for antimicrobials and would allow Medicare to reimburse qualifying hospital-administered antibiotics used to treat serious or life-threatening infections.

EBOLA ERADICATION ACT OF 2019:

The Ebola Eradication Act was introduced by Senator Bob Menendez (D-NJ) in May 2019 and directs USAID to support efforts in the DRC, South Sudan, and Burundi to combat the ongoing Ebola outbreak.³⁹ The Senate passed the act in September 2019 (S.1340) by unanimous consent, authorizing activities to combat the Ebola outbreak in the DRC.⁴⁰ At time of writing, it awaits action in the House of Representatives.

FLU VACCINE ACT:

The Flu Vaccine act was introduced by Congresswoman Rosa DeLauro (D-CT) and Senator Edward Markey (D-MA) in February 2019.⁴¹ The Flu Vaccine Act calls for \$1 billion (\$200 million annually for fiscal years (FY) 2020 through 2024) to support the National Institutes of Health's (NIH) efforts to develop a universal flu vaccine.



As a leader in Congress of bipartisan efforts to strengthen international and domestic public health security preparedness and response programs, I believe Congress must maintain this momentum by continuing to address pressing health security issues, including vaccine hesitancy. Vaccinating children against deadly diseases, such as measles, is essential to U.S. health security, and I am committed to improving our efforts to reach parents with quality science and win their trust and confidence."

— U.S. Congresswoman Anna Eshoo (D-CA-18)

THE LOWER HEALTH CARE COSTS ACT OF 2019: The Lower Health Care Costs Act was introduced by Health, Education, Labor and Pensions (HELP) Committee Chairman Senator Lamar Alexander (R-TN) and Ranking Member Senator Patty Murray (D-WA) in June 2019 and reported out of the committee with broad bipartisan support in July 2019.⁴² The bill includes provisions addressing vaccine hesitancy and strengthening public health data management, both of which are included in companion legislation in the House of Representatives.

PANDEMIC AND ALL-HAZARDS PREPAREDNESS AND ADVANCING INNOVATION ACT (PAHPAI) OF 2019: In June 2019, President Trump signed PAHPAI into law.⁴³ PAHPAI was originally introduced in the House by Energy and Commerce Health Subcommittee Chairwoman Anna G. Eshoo (D-CA) and Congresswoman Susan Brooks (R-IN) and by Senators Richard Burr (R-NC) and Bob Casey (D-PA) in the Senate. The legislation reauthorizes and builds upon public health preparedness and response programs at the U.S. Department of Health and Human Services (HHS) and the CDC. PAHPAI authorizes \$611.7 million for the Biomedical Advanced Research and Development Authority (BARDA) to implement strategic activities to address a range of public health security threats, including pandemic influenza and AMR, a \$50 million increase over FY 2019 funding levels.⁴⁴ This increased investment will further support BARDA in the develop-

ment of surveillance technology, diagnostics, and countermeasures for emerging and high-consequence infectious diseases with pandemic potential.

VACCINE AWARENESS CAMPAIGN TO CHAMPION IMMUNIZATION NATIONALLY AND ENHANCE SAFETY (VACCINES) ACT OF 2019: The VACCINES Act was introduced in May 2019 by Representatives Kim Schrier (D-WA), Michael Burgess (R-TX), Eliot Engel (D-NY), Brett Guthrie (R-KY), Kurt Schrader (D-OR), and Gus Bilirakis (R-FL) and Senators Gary Peters (D-MI), Pat Roberts (R-KS), and Tammy Duckworth (D-IL).⁴⁵ The VACCINES Act authorizes \$6 million annually for FY 2020 through FY 2024 for the CDC to study and monitor vaccine hesitancy and conduct an expanded public awareness campaign on the importance of immunizations.

VACCINE INFORMATION AND PROMOTION (VIP) ACT OF 2019:⁴⁶ The VIP Act was introduced in June 2019 by Representatives Sheila Jackson Lee (D-TX), Eleanor Holmes Norton (D-DC), Gwen Moore (D-WI), Terri Sewell (D-AL), Ayanna Pressley (D-MA), Eddie Bernice Johnson (D-TX), Carolyn Maloney (D-NY), Donald Payne Jr. (D-NJ), and Lucy McBath (D-GA). The VIP Act authorizes \$50 million annually for FY 2020 through FY 2024 for HHS to counter the rise of vaccine hesitancy through expanded vaccination education programs, public awareness, and communications campaigns.



"Health security challenges are innately complex, and require all of us working together, across agencies, jurisdictions, and even across countries, to come together and form a better line of defense. No government or private company or NGO can solve them alone. We have to come together in private-public partnerships to overcome these formidable challenges."

— Julie Gerberding, Merck & Co, Inc.

The executive branch has made considerable policy progress, as evidenced recently in the evolution of the Global Health Security Agenda (GHSA), the issuance of the updated National Biodefense Strategy in 2018—aided by the high-quality work of the Bipartisan Commission on Biodefense—and the White House Global Health Security Strategy in 2019.^{47,48}

it also fully recognizes the vital importance of investing in domestic public health infrastructure and preparedness, which continue to lag dangerously behind what is required to protect Americans.

In this respect, the Commission complements the work of the Bipartisan Commission on Biodefense (formerly known as the Blue Ribbon Study Panel on Biodefense), which assesses and provides recommendations on strengthening the state of U.S. biodefense. It is critically important that the U.S. government invest at a higher level, on a sustained basis, in state and local public health capacity, as these officials will be on the front lines in the case of an outbreak in the United States.

STRENGTHENING DOMESTIC PREPAREDNESS

This report highlights actions the U.S. government can take to counter health security threats around the world. Even as the Commission emphasizes the importance of stemming disease beyond U.S. borders,



"We have seen time and again that diseases do not respect national borders. We have to act simultaneously at home and abroad. At the same time that we invest in global preparedness, we must also focus on the needs within our borders: strengthening leadership, coordination, and funding to respond to public health and biological threats at home."

— Peggy Hamburg, National Academy of Medicine



"Real-time data at the fingertips of decision makers on the front lines of an epidemic speeds response efforts. The U.S. government has promoted the use of digital health tools to improve collection, analysis and use of health data, but more effort is needed by the United States and others to ensure these technologies are effectively used and safeguards for data sharing are in place prior to a crisis."

— Steve Davis, PATH

We have seen exceptional innovations emerge from the 2014-2016 Ebola crisis in West Africa, led by the private sector. An experimental Merck vaccine developed in that period underpins today's Ebola response in the DRC, where more than 230,000 persons have been immunized as of October 2019.⁴⁹ A second Ebola vaccine by Johnson & Johnson, also first developed in West Africa, is now being introduced on an experimental basis in Uganda and the DRC.⁵⁰

More recently, randomized field trials of four experimental Ebola treatments conducted during the DRC outbreak have produced preliminary results indicating that two therapies, one developed by Ridgeback Biotherapeutics and the other by Regeneron Pharmaceuticals, can significantly increase survival if administered early.⁵¹ Both therapies are public-private partnerships, with the National Institute of Allergy and Infectious Diseases (NIAID), BARDA, and the Department of Defense (DOD) all playing key supporting roles.⁵² Together, these promising therapies have the potential to change the course of Ebola outbreaks. For the immediate crisis in the DRC, that will require overcoming chaos and violent disorder, including violent, opaque networks attacking health providers; creating a far better dialogue with mistrustful, alienated communities; and better motivating citizens to step forward early to seek treatment.

That same Ebola crisis of 2014-2016 inspired the creation of the Coalition for Epidemic Preparedness Innovations (CEPI), an alliance comprised of governments, foundations, companies, non-profits, and researchers, with a mandate to finance and coordinate the development of new vaccines to

prevent and contain infectious disease epidemics.⁵³ CEPI is off to a promising start in its first two and a half years, investing \$456 million in new partnerships with the private sector, academic institutions, and other non-profit product development enterprises to develop new vaccines.⁵⁴ It is a particularly compelling innovation in health security.

DIGITAL HEALTH AND HEALTH SECURITY

Timely and accurate information to assess disease burdens, track emerging outbreaks, and support disease prevention and control measures is essential in epidemic response. Over the past decade, countries have increasingly transitioned from paper-based to digital information systems and have gained new capabilities and insights by engaging in the corresponding data. When optimized, the convergence of digital technologies and new data models with health systems, also known as "digital health," can allow countries to make more accurate and timely decisions for preventing, detecting, and responding to outbreaks.⁵⁵

While clear successes have resulted from these initial efforts, significant challenges remain, including corruption, lack of transparency, and distrust of commercial firms.⁵⁶

- Many health information systems are siloed and capture duplicate data, putting significant strain on

health workers who collect, manage, and use this information.

- Health information systems are not always interoperable. Their inability to reliably "talk" to one another hinders evidence-based decisionmaking.
- Many low- and middle-income countries need to boost stakeholders' capacity to design, manage, and support digital health systems, as well as effectively use data.
- Many countries lack the necessary governance structures, policies, and coherent national plans to ensure transparency and accountability, guard against corruption, and support the utilization of data to inform epidemic response decisions and actions.
- The U.S. government has not sufficiently leveraged the American technology sector's potential to advance digital health and global health security goals. Part of that process involves building trust and confidence in private-sector partners.

The United States, in collaboration with private-sector technology partners, is a global leader in creating and adopting digital health technologies for epidemic response. The U.S. government is in a strong position to leverage its resources and build on proven strategies to meet existing gaps that are prohibiting true scaling of digital technologies. Deploying these technologies and ensuring coordination with global and national partners can ensure that the necessary data and information are available in the right place, at the right time, and to the right people to speed epidemic response.

A U.S. Doctrine of Continuous Prevention, Protection, and Resilience

The seven recommendations below will enable the United States to replace the crisis-complacency cycle with a doctrine of continuous prevention, protection, and resilience—investing strategically in preparedness now so the United States can manage threats and avoid catastrophic costs later.

The doctrine aims to restore White House leadership, strengthen financing and the speed of response, build reliable partners abroad, enhance the U.S. government's ability to operate in disordered settings, and accelerate technological innovations to secure the future. It aims to strengthen accountability, prioritization, and reform of fragmented programs.

The Commission urges Congress and the administration to pursue the following integrated package of actions:



1. Restore health security leadership at the White House National Security Council.

RECOMMENDATION

The U.S. government should re-establish a directorate for global health security and biodefense on the National Security Council (NSC) staff and should name a senior-level leader in charge of coordinating U.S. efforts to anticipate, prevent, and respond to biological crises. These actions will ensure that the necessary leadership, authority, and accountability is in place to protect the United States from a deadly and costly health security emergency.



"Health security is fundamental to U.S. national security. It is encouraging that despite a polarized U.S. Congress, this is an area where we have made meaningful progress on a bipartisan basis. We all have an interest in national security, in our health, and in making sure that we do the right thing to protect the American people."

RATIONALE

Global health security and biodefense challenges pose a national security threat to the American people and require centralized leadership at the highest level of the U.S. government. While the administration has released its National Biodefense Strategy and Global Health Security Strategy and strengthened the roles of departments and agencies, top-level leadership is still needed at the White House. Global health security threats touch the equities of multiple executive agencies—including the Departments of State, Health and Human Services, Defense, and Justice, as well as the intelligence community—and require informed, coordinated attention to an array of capabilities and responses spanning medical technologies and public health interventions, intelligence gathering and preemption, and sustained high-level diplomacy to mobilize international coalitions. By definition, this zone of national security requires a strong interagency process led by the White House.

In the fall of 2016, in the aftermath of the slow, uncoordinated, and resource-intensive response to the Ebola crisis in West Africa, the White House NSC staff created the Global Health Security and Biodefense directorate. Designed to plan for and oversee rapid, efficient, government-wide responses to global health security threats, the directorate pooled NSC staff focused on domestic and international biodefense and health security issues. Led by a senior director, the directorate reported to the national security advisor and the deputy homeland security advisor, the latter of whom was designated as the lead for coordinating the U.S. response to a biological crisis. The White House also released a companion executive order in November 2016 advancing the GHSA.⁵⁷

In the spring of 2018, the administration dissolved the NSC directorate for Global Health Security and Biodefense, and

— Kelly Ayotte, Former Senator (R-NH)

oversight of these issues was incorporated into the directorate for Weapons of Mass Destruction and Biodefense.⁵⁸ In the fall of 2018, the White House released a National Biodefense Strategy designed to strengthen the country's defenses against biological threats to health and safety.⁵⁹ President Trump also signed a National Security Presidential Memorandum on Support for National Biodefense, which reaffirmed U.S. support for the GHSA, extending through 2024, and established a Biodefense Steering Committee chaired by the secretary of Health and Human Services and responsible for the monitoring, coordination, and implementation of the strategy.⁶⁰ In May 2019, the White House released a Global Health Security Strategy, the first of its kind, which "defines the actions the Administration will take to prevent, detect, and respond to infectious disease threats, whether naturally occurring, accidental, or deliberate," and which reiterated the administration's support for the GHSA.⁶¹

The administration should be commended for advances in the national biodefense and global health security strategies. However, critical leadership gaps remain. It remains unclear who would be in charge at the White House in the case of a grave pandemic threat or cross-border biological crisis, whether natural, accidental, or deliberate. Over the past year, the sluggish White House response to the Ebola outbreak in the DRC is but the latest example of this problem.

And while the Biodefense Steering Committee plays an important role in implementing the National Biodefense Strategy, senior leadership in the White House is required to successfully coordinate the large number of government agencies and programs across health, security, development, and defense, as well as private-sector actors that

would be involved in a response to an international public health threat. In the case of a health security emergency, White House leadership will also be critical in navigating challenging political issues like quarantines and travel bans and in communicating to and reassuring the American public. The authorities currently in place at HHS are insufficient to address these critical, complex, and often urgent interagency demands.

In addition to coordinating the interagency process, a global health security and biodefense directorate at the NSC can reform fragmented programs and ensure higher efficiencies, strengthened accountability, and better spending of scarce resources. Together with the Office of Management and Budget (OMB), it can identify, rationalize, and align funding in the U.S. president's budget across agencies.

ESTIMATED COST: N/A



2. Commit to full and sustained multi-year funding for the Global Health Security Agenda to build partner capacity.

RECOMMENDATION

U.S. direct investments remain essential to build health system capacity. To stop outbreaks at the source, Congress should authorize stable funding through the GHSA's 2020-2024 phase for capacity-building programs in priority countries, including the original 17 GHSA partner countries, plus other select high-risk countries, such as the DRC. Experts advise that this will involve returning the GHSA-re-



"To contain a naturally occurring outbreak, a lab accident, or a bioterrorist attack, the first response has to be the health system that identifies the pathogen, does the surveillance, finds its origin, and promotes measures to limit its damage. We must expand and sustain funding for the GHSA, the world's vehicle for building resilient public health infrastructure."

— Ambassador Jimmy Kolker, U.S. Department of Health and Human Services (former)

lated budgets of the principal executive agencies implementing the GHSA (the CDC, USAID, the U.S. Department of State, and the DOD) to FY 2015 baseline levels, with Ebola supplemental funding.

RATIONALE

The GHSA is a multi-partner initiative that facilitates burden sharing and builds local health system capacity.⁶² The \$1 billion in emergency supplemental funding that the U.S. government has committed to the GHSA so far (FY 2015-FY 2019) has gone a long way in helping countries to prevent or stem the spread of infectious disease outbreaks.⁶³ The question now is what comes next, as the emergency supplemental funding ends at the conclusion of FY 2019.

A cornerstone of the effort is the voluntary, collaborative assessment process designed to measure a country's capacity to prevent, detect, and rapidly respond to public health threats.⁶⁴ These assessments, known as Joint External Evaluations (JEEs), have been conducted in 100 countries in six regions since the GHSA was launched in 2016, and 21 additional JEEs are scheduled as of this

writing.⁶⁵ Most of these assessments have been published to facilitate understanding and enable urgent gaps to be filled. The United States has been actively engaged in the JEE processes, participating in JEE missions and providing technical support to countries as they develop National Action Plans. The GHSA Private Sector Roundtable brings the private sector into this process by connecting GHSA countries with companies in the health care, finance, technology, and logistics sectors.⁶⁶

Several U.S.-assisted GHSA countries have experienced infectious disease outbreaks in recent years, and the improved health system and preparedness capacities built with the help of U.S. agency support and other international partners have proven decisive. In October 2017, a U.S.-assisted laboratory confirmed a positive case of Marburg virus in eastern Uganda. Marburg is a lethal virus in the same family as Ebola, and this laboratory confirmation proved the first critical step in a rapid and effective Uganda-led response. The Uganda Ministry of Health deployed a rapid response team to the affected region, which was staffed in part by U.S.-supported Field Epidemiology Training Program (FETP) graduates. Ultimately, three cases were confirmed, all of



which were fatal. But through effective contact tracing and community education, the Ugandan rapid response team stopped the spread of the virus.⁶⁷

Fully funding the GHSA into the future will help the U.S. government stop outbreaks at their source—the best way to protect the American people. As the emergency supplemental funding comes to an end, there are funding gaps that should be addressed. Experts estimate that an additional \$100 million per year above the enacted FY 2019 budget will be required for the CDC, and an additional \$35 million per year for USAID. These investments should be understood as part of a 10-year strategy for building self-reliance among partner countries.

As part of that investment, the CDC and USAID should give serious consideration to investing \$20 million per year to strengthen digital health information systems in priority countries.⁶⁸ In today's digital world, interoperable health information systems are becoming essential to facilitate evidence-based decisionmaking. That requires effective regulatory and legal oversight to ensure transparency and accountability; surveillance and laboratory systems to track emerging outbreaks and support disease control measures; digital monitoring of supply chains to ensure commodities are available when needed; and monitoring of vaccine and therapeutic delivery.

Key programs within the Departments of Defense and State should also be protected and sustained. These include the DOD Cooperative Threat Reduction (CTR) Biological Threat Reduction Program (CTR/BTRP), DOD Global Emerging Infections Surveillance and Response (GEIS) Program, and the State Biosecurity Engagement Program (State/BEP). These budgets support global health security efforts aimed

at preventing deliberate and accidental outbreaks, linking law enforcement and public health officials, and detecting emerging threats as early as possible.

ESTIMATED COST:^c

CDC: \$100 million beyond FY 2019 levels (annually for 10 years).

USAID: \$35 million beyond FY 2019 levels (annually for 10 years).

C. Refer to Appendix I: Illustrative Costing for Recommended Programs and Initiatives for illustrative costing of all recommendations outlined in this report.

THE DOD AND HEALTH SECURITY

The DOD contributes to overall U.S. health security through a number of programs that are aimed at countering biological threats from all sources.⁶⁹

U.S. military medicine has a long history of landmark successes against tropical diseases affecting troops from temperate zones operating in tropical environments. Examples include the efforts against yellow fever, which were led by U.S. Army Majors Walter Reed and William Gorgas during the Spanish American War, and extensive epidemiological studies during the 1918 worldwide influenza epidemic.

Today, the DOD operates a worldwide public health, infectious disease research, and disease surveillance network to protect U.S. and allied forces against



"Historically, more military service members have died from dangerous infectious disease than from bullets. Over the last century, the U.S. military has made extensive investments to protect U.S. and allied forces from health security threats and confront and defeat these global threats."

These investments remain essential to protect both the military and the general public."

— Admiral Jonathan Greenert, U.S. Navy (former)



"Global health security is national security. If we want to see truly strengthened health security, we need to better integrate the Department of Defense's unique research, mobility, and security capacities."

—General Carter Ham, U.S. Army (former)

infectious diseases and other biological hazards. These extensive programs benefit both the military and the general public.⁷⁰ A few examples include:

- The U.S. military GEIS Program, established in 1997, works closely with the DOD overseas and domestic infectious disease research laboratories, the CDC, the WHO, and others.⁷¹
- The Defense Threat Reduction Agency's (DTRA) Biological Threat Reduction Program (BTRP) supports international partnerships and capacity-building efforts to combat the threat of intentional, accidental, and naturally occurring biological threats.⁷² BTRP works closely with regional geographic combatant commanders (GCCs) to support activities in Asia, Africa, the Middle East, and Europe. These efforts have become increasingly coordinated with activities of other programs and organizations aligning with international frameworks, such as the IHR and the GHSA
- The Military Infectious Diseases Research Program (MIDRP) manages research on naturally occurring infectious diseases, focusing on the development of vaccines and drugs, diagnostics, and vector control on illnesses most likely to impact military operations. MIDRP supports basic science, preclinical studies, and clinical trials leading to Federal Drug Administration (FDA) approval. Most of this work is carried out at DOD laboratories located in Maryland—the Walter Reed Army Institute of Research (WRAIR), the U.S. Naval Medical Research Center (NMRC), and the U.S. Army Research Institute of Infectious Diseases (USAMRIID)—as well as the overseas DOD laboratories located throughout the world.
- The DOD supports many other activities developing detection capabilities, medical countermea-

sures, and personal protective equipment against biological threats.

- Finally, U.S. military forces are available for disaster response anywhere in the world when necessary to augment civilian capabilities. Operation United Assistance, the DOD support for the U.S. government response to the Ebola outbreak in Liberia in 2014-2015, is the most recent and prominent example.



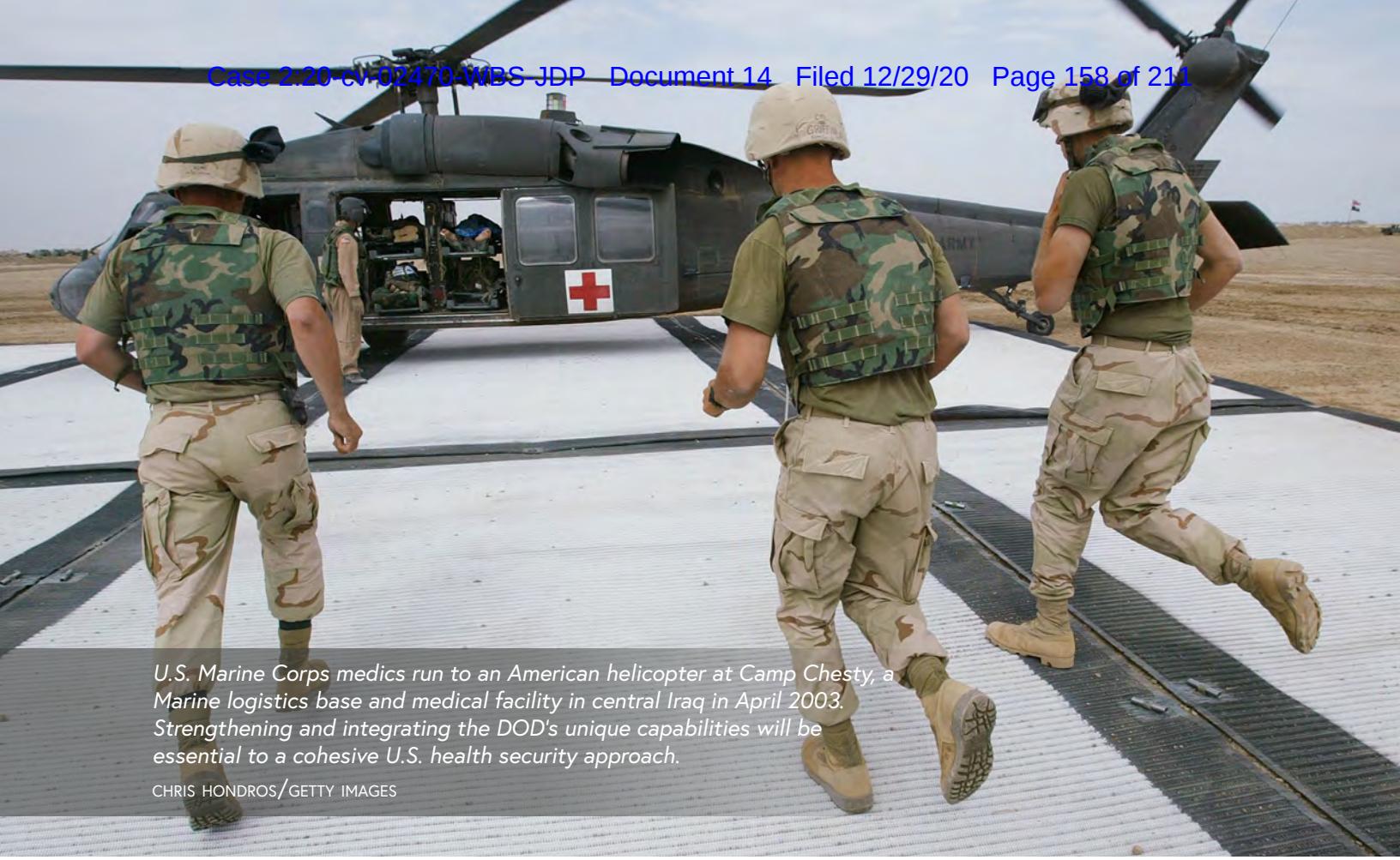
3. Establish a Pandemic Preparedness Challenge at the World Bank to incentivize countries to invest in their own preparedness.

RECOMMENDATION

U.S. multilateral leadership is necessary to address the financing gap for preparedness, one of the steepest problems in health security. Linked to its support for the GHSA 2024 framework, in FY 2020 the U.S. government should assemble an international consortium of public and private donors to launch a five-year, \$750 million Pandemic Preparedness Challenge to catalyze domestic investment in health security preparedness in the 32 fragile states eligible for financing from the World Bank's International Development Association (IDA). The United States would pledge one-fifth of the donor shares, leveraged against contributions by other donors of the remaining four-fifths.

RATIONALE

The financing gap for preparedness is one of the steepest problems in health security, especially among fragile states. The lack of preparedness in fragile and conflict-affected states—where infectious disease outbreaks are increasingly common—directly impacts and threatens



U.S. Marine Corps medics run to an American helicopter at Camp Chesty, a Marine logistics base and medical facility in central Iraq in April 2003. Strengthening and integrating the DOD's unique capabilities will be essential to a cohesive U.S. health security approach.

CHRIS HONDROS/GETTY IMAGES



"As the 2014-2016 West Africa Ebola crisis reminded us, pandemics do not respect national borders. The only long-term, sustainable solution is for governments to invest in their own preparedness. We are determined to push forward to motivate countries to address this glaring financing gap."

— U.S. Senator Todd Young (R-IN)

U.S. economic, health, and national security interests. Investments in preparedness are cost-effective and affordable, but many fragile state governments continue to underinvest at dangerously low levels. In the poorest and most fragile countries, where many needs are pressing and resources are constrained, political leaders often face difficult trade-offs between investing in longer-term preparedness versus shorter-term, more tangible efforts like building roads or schools.

However, experience suggests that with the right incentives and support, developing countries will invest their

money in preparedness. In Uganda, Cameroon, Ethiopia, Vietnam, and Cambodia, for example, the governments have drawn upon their own budgetary resources and talent to bolster their preparedness, with support provided by donors under the GHSA framework. While there are several multilateral mechanisms in place to support emergency outbreak responses, much more effort is needed to partner with countries to invest in their own long-term preparedness.

Thirty-two countries eligible for IDA financing, with a total population of about 400 million people, are classi-

fied by the World Bank as fragile and conflict-affected states.⁷³ As of August 2019, 24 of these countries have completed JEEs of their preparedness gaps, and 15 have developed National Action Plans to address those gaps.⁷⁴ Yet most of these countries are unable to marshal sufficient domestic resources to fully fund their National Action Plans, rendering their health and preparedness systems acutely vulnerable.

To help fragile countries turn their plans into reality and build self-sustaining capacities, Congress should press the U.S. government to partner with public and private donors to launch a five-year, \$750 million Pandemic Preparedness Challenge. The United Kingdom, Germany, Japan, France, Australia, Finland, Denmark, and Sweden would likely be strong partners in this effort. Saudi Arabia, the United Arab Emirates, South Korea, and others might join as well.

Administered by the World Bank, the Challenge will work in tandem with IDA financing to supplement direct investments by states themselves in capital and operational costs to strengthen preparedness. Countries whose plans and budgets are approved by the Challenge's board may be awarded up to a maximum of five years of grant funding to cover start-up and recurrent costs.

To promote self-reliance and sustainable domestic financing, the Challenge investments will be time-bound and will cover a declining share of a country's recurrent costs each year (e.g., up to 80 percent in year one and 20 percent by year five). Each Challenge country will have an exit strategy, with success measured by increases in JEE scores over the life of the investment plan. The U.S.

government's share of the Challenge will be \$150 million, or \$30 million a year for five years, for a 1:4 leverage with other donor funding.

ESTIMATED COST:

\$30 million per year for five years.



4. Ensure rapid access to resources for health emergencies.

RECOMMENDATION

To ensure that flexible funds are available early in a crisis, the USAID and CDC contingency accounts should be set and maintained at a level of \$250 million each, replenished annually as needed. The United States should also pledge \$25 million annually to the WHO Contingency Fund for Emergencies (CFE), using that contribution to leverage other donors to bring the CFE to its targeted \$100 million level.

RATIONALE

Stopping a global health security crisis requires fast, early action. Today, demand for such action is swiftly rising as the number of major health and humanitarian crises increases, as can be seen in the DRC, Venezuela, Yemen, Afghanistan, and Syria. Expanding support for contingency funds will allow the United States to support emergency response activities by nongovernmental and international organization partners in insecure and disordered settings, where direct engagement by U.S. agencies may be more difficult or simply not feasible.



"Investing in global health security helps to ensure that the world remains a safe place and American citizens are protected from harm. To stop outbreaks at their source, we need rapid response contingency funds and we need to help other countries to invest in their own preparedness. Through the appropriations process, Congress has worked on a bipartisan basis to ensure that funding goes to countries to build and sustain health security preparedness."

— U.S. Congressman Tom Cole (R-OK-4)

In the aftermath of the slow and cumbersome response to the 2014-2016 West Africa Ebola outbreak, the U.S. government recognized the clear need for contingency funds that could be readily accessible in the case of an infectious disease emergency. A second major lesson learned from the 2014-2016 Ebola outbreak is that the CDC and USAID each play a unique and essential role in a global health security crisis, and neither is sufficient on its own. The resulting establishment of the CDC Infectious Diseases Rapid Response Reserve Fund and the USAID Emergency Reserve Fund for infectious disease outbreaks was a significant first step in addressing the gap in quick-disbursing finances.

However, independent experts have estimated that the USAID and CDC contingency accounts, at their current levels, are not sufficient to respond to the increasing number and intensity of global health crises. In FY 2019, \$50 million was appropriated for the CDC contingency fund, and \$2 million for the USAID contingency fund.^{75,76} Experts recommend that these accounts be set and maintained at a level of \$250 million each, replenished on an annual basis as warranted. It will be important to amend current policies to permit rapid disbursement of these funds during the early stages of infectious disease outbreaks.

In parallel, a U.S. annual pledge of \$25 million to the WHO CFE will significantly bolster the WHO's capacity to move expeditiously in deploying staff and funding early responses to dangerous outbreaks. A contribution to the WHO CFE will allow the United States to support emergency response activities by NGOs, national governments, and international organizations in difficult-to-access settings where direct U.S. government engagement is not possible. The United States should use that contribution to leverage other donors to

contribute to achieving and maintaining a \$100 million CFE. No less important, the United States should prioritize expanding and ensuring sufficient financing flexibility and speed in the World Bank's emergency response facilities.

ESTIMATED COST:

CDC Infectious Diseases Rapid Response Reserve Fund:

Fund: Increase to \$250 million and maintain at that level.

USAID Emergency Reserve Fund:

Increase to \$250 million and maintain at that level.

WHO Contingency Fund for Emergencies: \$25 million per year.



5. Establish a U.S. Global Health Crises Response Corps.

RECOMMENDATION

To engage and operate effectively and safely in austere, unsafe settings, the U.S. government should establish a U.S. Global Health Crises Response Corps. The Corps should be constructed on USAID and CDC existing capabilities, augmented by joint team training exercises, and provided with security, intelligence and data, and communications support. The mandate of the Corps is to respond early, with local partners, to stop outbreaks at their source and to strengthen local capacities.

RATIONALE

Small teams of select, highly experienced U.S. civilian public health and humanitarian experts, working alongside local partners and national leaders, form the "cerebral cortex" of outbreak response.



"Today the world faces a volatile convergence of instability, state weakness, and conflict. These conditions are hindering the ability of the United States to support health service delivery and outbreak response in a number of critical regions. We need to be able to deploy our best and brightest civilian experts into disordered settings where outbreaks strike."

— *Rebecca Hersman, CSIS*

CDC civilian experts provide on-the-ground interpretations of fast-moving, complex outbreaks and immediate advice on the precise mix of public health interventions, geographic priorities, and communications with communities and partners necessary to halt outbreaks. In addition, the CDC possesses essential expertise in epidemiology, data systems, contact tracing, and training of the local health work force.

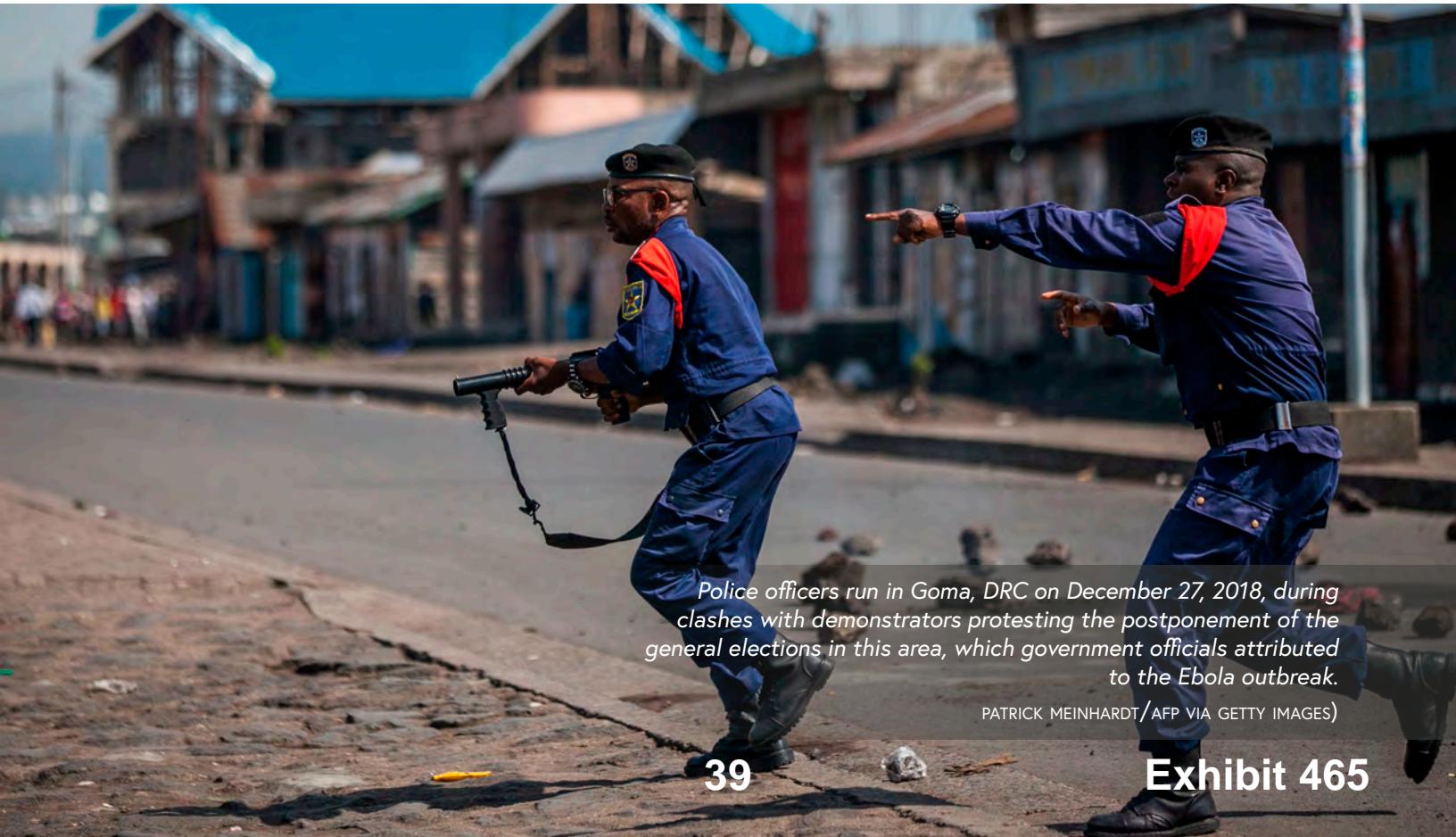
The USAID Disaster Assistance Response Team (DART) platform, refined over the past three decades, has developed protocols and operational capacities to integrate the CDC, the Department of State, and others, as well as to interface with the U.S. military, as needed, in deploying into humanitarian emergencies.⁷⁷ USAID has essential aptitudes in large-scale logistics, contracting, and supply chain management and expertise in the critically important development sectors of water, food, and health infrastructure.

Their combined presence can be a high-impact game changer, as witnessed in the Ebola outbreaks in West Africa in 2014-2016. Inversely, when U.S. and other critically important experts are barred from outbreak zones due to insecurity, as currently seen in the DRC, disease may spread, with grave consequences.

The world has grown more perilous, and the worst danger zones are precisely where the greatest health security risks frequently reside. Yet risk aversion has impeded USAID and CDC deployments into several outbreak zones, including the DRC, South Sudan, Iraq, Syria, and Nigeria, while Yemen and Afghanistan offer only minimal access. Moreover, danger is not likely to abate in the future. If anything, it will worsen. Policymakers are understandably cautious—but failing to engage is ultimately trading one risk for another. The United States simply cannot afford to leave its key civilian capabilities on the sidelines of rapidly emerging health crises.

In combination, U.S. civilian teams from the CDC and USAID are often able to engage partner governments, civil society, and other nongovernmental providers far more authoritatively and bluntly than the WHO. Their unique impact warrants assuming higher risks than might otherwise be the case, along with making higher investments in training, support, and protection.

The Corps will be drawn from the ranks of current U.S. public health and humanitarian experts in the CDC, USAID, and the U.S. Public Health Service. The majority, it is expected, will have significant experience serving on USAID-led DART teams and as members of the CDC Global



Rapid Response Team (Global RRT). They will receive special training and be on-call to deploy, as needed, in civilian expeditionary teams introduced for rotational assignments away from their normal duties into insecure environments. The Corps will have two tiers: Fifty highly experienced and highly trained advanced responders will be committed to deploy as teams on very short notice; and 400-500 experts will be available for deployments that can be made with careful prior planning.

The Corps will bring to the field public health expertise and operational experience in select, vitally important disciplines: incident and data management; community engagement to build trust and confidence; epidemiology; laboratory-based pathogen surveillance; and emergency humanitarian response services, including in non-health areas such as water, food relief, and shelter. The Corps should systematically invest in strengthening the capacity of local, in-country, and regional partners, including NGOs and civil society groups. Though not intended to deliver clinical health services, it can play an essential role in facilitating and expediting service delivery by local partners.

The Corps will be trained to deploy into gray zone settings prone to intermittent, localized violence that falls below the level of open armed conflict conducted by armies and irregular forces. Teams from the Corps will be equipped to deploy to two to three countries in the first one to two years. The teams will be charged with aligning their work in support of partner institutions and agencies, including the host nation, the WHO and related UN bodies, and operational NGOs.

All members of the Corps will receive training in operating as structured teams, critical languages (experts recommend French, Arabic, Portuguese, and Spanish), negotiation of local access, communications, use of local intelligence, building trust with local communities, means to minimize risks and optimize protection, and entry and extraction protocols. Training will emphasize speed and self-sufficiency in deployment, and it will be critical to ensure unencumbered access to critical supplies.

For the Corps to operate in insecure circumstances will require overt acknowledgement of the need to accept significant risks when the risks of not acting are grave. It will also require acknowledgement of the need for the Corps to receive quality, real-time, granular intelligence. To rebalance risk calculations, Congress or the administration should issue a policy statement declaring that putting U.S. civilian health response experts on the frontlines of health

crises is a compelling U.S. national security interest.

Follow-on steps will be needed to clarify what that means in practice in terms of revised risk calculations.

As envisioned, security will be managed on a case-by-case basis. It should be provided by the UN, host nation forces, or local police forces. The Corps will include appropriate DOD advisers, but will not call for DOD to provide security forces.

Depending on the specific situation, either the CDC or USAID should be designated as the lead agency with lead operational responsibilities, acting in close partnership with the other. The lead agency will direct a dedicated interagency process that deliberates over when to engage in public health emergencies and at what level, linked to metrics such as: severity of the outbreak; levels of insecurity and risk of escalation; health and security risks to the population and health personnel; whether there is a PHEIC declaration; and other international, regional, or national security factors. The lead agency will be charged with coordinating recruitment, training, and deployment of the Corps. It will be critically important that the relationship between the CDC and USAID be more constructive and functional. To that end, it will be important to clarify the specific roles and responsibilities of the CDC and USAID within an agreed response framework.

Ultimately, the White House will decide when and where to deploy, based on close consultation with the CDC director, the USAID administrator, the Department of State and chief of mission in the affected country, relevant Department of State security personnel, and DOD personnel, as well as through consultations with the WHO and the host government. Teams will not be deployed without host government request or consent and will deploy under the authority of the chief of mission, except under extraordinary conditions. It will be necessary to develop protocols that establish the security parameters under which the chief of mission could authorize deployment of the Corps.

ESTIMATED COST:

U.S. Global Health Crises Response Corps: \$50 million per year for five years.

Strengthening the FETP, the Public Health Emergency Management (PHEM) Fellowship program, and National Public Health Institutes (NPHIs): \$36 million per year for five years.



"The U.S. government has unrivaled civilian and military capabilities in detecting, preventing, and responding to global health security threats, but these capabilities don't always achieve jointness. Ensuring joint training, exercises, and deployment will only strengthen the U.S. global health security posture."

— Ambassador Karl Hofmann, Population Services International



6. Strengthen the delivery of critical health services in disordered settings.

The United States should strengthen, refocus, and adapt programs and capacities to ensure the continuity and expansion of necessary health services, including the delivery of immunizations, gender-based violence (GBV) programs, and maternal and reproductive health and family planning services in crisis settings. The health and protection needs of acutely vulnerable women and girls should be prioritized.

Immunization Programs

RECOMMENDATION

The U.S. government should lead an effort to strengthen immunization programs in disordered settings through an improved comprehensive data system to anticipate and prevent vaccine-preventable disease (VPD) outbreaks, particularly in fragile and conflicted countries; rapid response funding to likely outbreak “hotspots”; and enhanced training programs to build the capacity of community health workers operating in disordered settings to deliver immunizations.

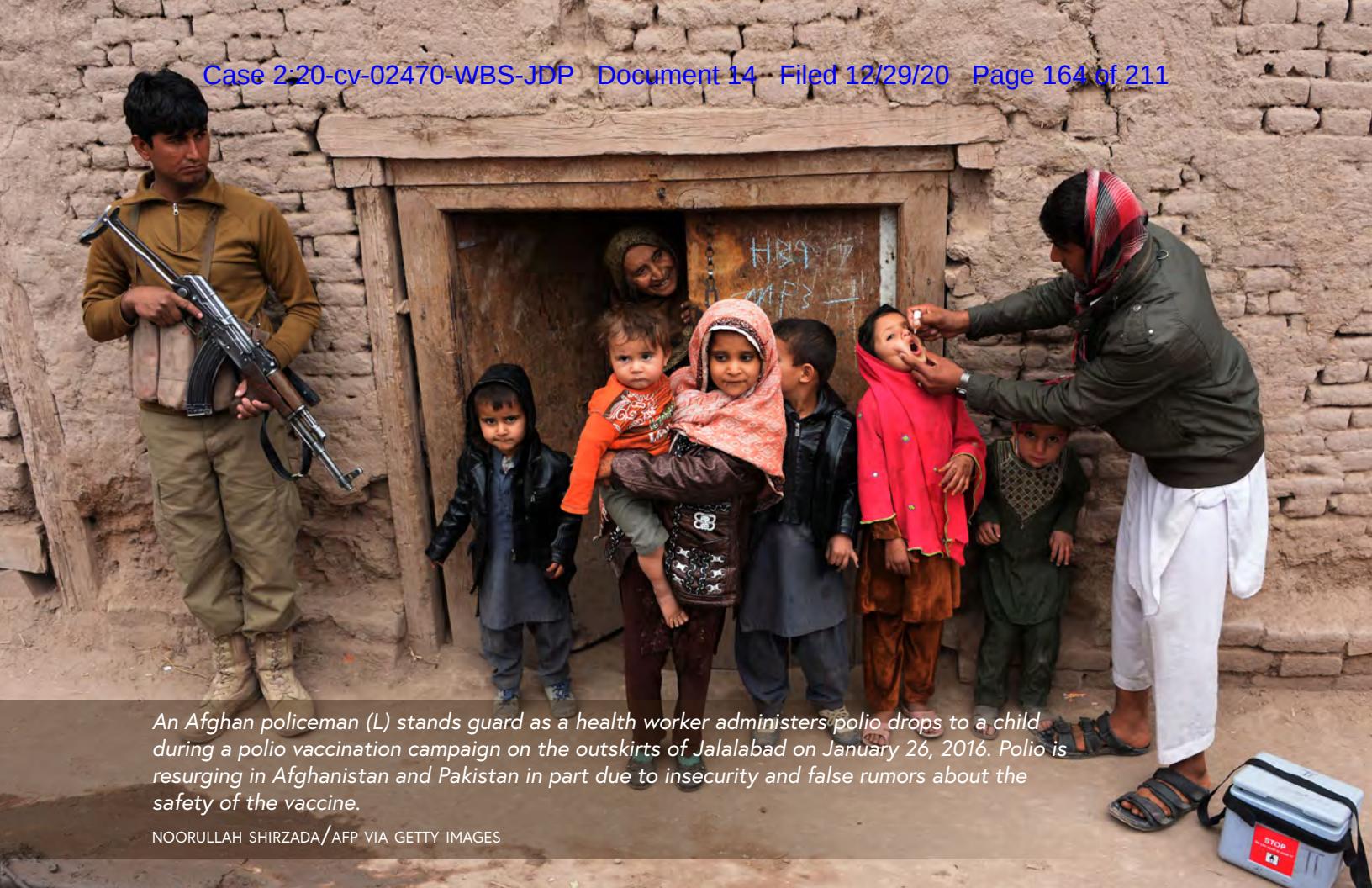
RATIONALE

Disorder disrupts immunization programs, acutely impacting coverage and raising the risks of outbreaks. In 2017, at least 60 percent of children who were not reached with routine immunization services lived in just 10 countries, including 5 of the top 15 most fragile states in the world.⁷⁸ Twenty million people currently cannot receive vaccines due to weak primary health systems, poverty, unstable governments, and war.⁷⁹ VPD outbreaks are much deadlier in

disordered settings and have a greater probability of crossing borders into more secure environments.

Global immunization partners, including U.S. agencies, have long cooperated to monitor immunization coverage, assess outbreak potential, and mobilize resources and technical assistance to deliver vaccines in disordered settings.⁸⁰ The U.S. government funds global immunization programs at the WHO and the United Nations Children’s Fund (UNICEF), through the Department of State and the CDC, and at Gavi, the Vaccine Alliance, through USAID. At the January 2015 Gavi replenishment conference, the United States pledged \$1 billion for the 2015 to 2018 period, and it has approved a contribution of \$290 million in 2019.⁸¹ The United States should be prepared to make a robust, multi-year commitment at the 2020 Gavi Replenishment meeting in London as well. Through USAID, the DOD, and HHS, including the CDC and the NIH, the U.S. government also supports overseas immunization programs with bilateral development and research support, technical assistance, and participation in multilateral governing structures, such as the World Health Assembly, the Gavi Board, and the GHSA.

Strengthen Data: The U.S. government should strengthen data systems to enhance national immunization registries and anticipate outbreaks. A network of data hubs integrating geospatial, demographic, political, and health information will help the global community assist fragile countries in anticipating and mobilizing to prevent potential VPD outbreaks. This network could be modeled on USAID’s Famine Early Warning Systems Network (FEWS NET).⁸² The CDC should share its experience establishing the Atlanta-based Global Disease Detection Operations Center, where analysts monitor global polio



An Afghan policeman (L) stands guard as a health worker administers polio drops to a child during a polio vaccination campaign on the outskirts of Jalalabad on January 26, 2016. Polio is resurging in Afghanistan and Pakistan in part due to insecurity and false rumors about the safety of the vaccine.

NOORULLAH SHIRZADA/AFP VIA GETTY IMAGES



"Our ability to operate in insecure settings is contingent on our ability to strengthen health system capacity in insecure settings. The U.S. government needs to push to expand its work with international organizations and partner governments around the world to secure global preparedness."

— Tom Frieden, *Resolve to Save Lives*

developments and other outbreaks.⁸³ The capacities of the DOD GEIS Program and overseas research laboratories, the National Geospatial Intelligence Agency, and NASA's Goddard Space Flight Center should also be harnessed to contribute to this work, much as they contribute to FEWS NET. An expert estimate of the initial pilot cost of a comprehensive data system is \$4.77 million a year over five years.⁸⁴

Emergency Funds: The United States should designate emergency immunization funds that can be quickly deployed to assist countries in delivering immunizations to predicted "hotspots" and should urge implementing and donor countries, as well as multilateral agencies, to do the same. As a Gavi donor, the United States could advocate that Gavi incorporate the flexibilities necessary to release funds quickly in response to data warning of a

possible outbreak. The U.S. government should also have contingency funds available for emergency immunization activities.

An expert estimate of the necessary cost for emergency immunization funds is \$20 million a year over five years.⁸⁵ These funds could be drawn from the CDC Infectious Diseases Rapid Response Reserve Fund or the USAID Emergency Reserve Fund for infectious disease outbreaks, as needed and as appropriate. This report recommends these funds be set and maintained at a level of \$250 million each, ensuring ample funding for responding to immunization emergencies as well as other infectious disease emergencies (refer to Recommendation 4 for more detail).

Training Community Workers: The United States, through USAID and the CDC, should strengthen and expand agency contributions to training programs meant to enhance the capacity of community health workers to deliver immunizations and related services in disordered settings. Flexible emergency training mechanisms are critical to provide training at the community, subnational, and national levels and enable health workers in zones identified as “at risk” to gather on-the-ground information about community immunization coverage needs and work within the local security context to deliver vaccine products quickly and safely to vulnerable communities. Ensuring that trusted community and locally based health workers, rather than outsiders, can deliver vaccines is critical. An expert estimate of the initial cost of this training program is \$975,000 a year over five years.⁸⁶

The CDC should develop and deliver context-specific, short-term training modules preparing community health workers to assess and report on local immunization coverage and needs and deliver vaccines safely within disordered settings. This training should include a focus on culturally and linguistically competent messaging and effective communication to build vaccine confidence. This training could build on the FETP and the Stop Transmission of Polio (STOP) program, which is focused on VPDs.⁸⁷ The Training Programs in Epidemiology and Public Health Interventions Network (TEPHINET) and its parent organization, the Task Force for Global Health, link alumni of such initiatives as the CDC’s FETP with their counterparts across the world.⁸⁸ The CDC could work with partners within TEPHINET and the Task Force to embed experts within country immunization programs.

The USAID-supported CORE Group Polio Project, an international network of civil society groups and local community health organizations that provides financial and technical assistance to help countries eradicate polio and

address other infectious diseases, could also serve as a model in this area.⁸⁹ Some training initiatives could be integrated into existing CORE Group work.

ESTIMATED COST:

\$6 million per year for five years.

Health of Women and Girls

RECOMMENDATION

The U.S. government should prioritize women’s and girls’ health and protection in disordered and emergency settings. Congress should authorize \$30 million in flexible funding annually for five years to ensure that the extensive capacities of the U.S. government in the areas of maternal health, reproductive health, family planning, and GBV prevention and response are moved from the sidelines to the heart of crisis response.⁹⁰

This additional flexible funding is essential to spearhead this effort and incentivize U.S. agencies and their partners to rapidly begin execution of the program. The funding is intended to attract higher-level financial commitments from existing programs at USAID and the U.S. Department of State Bureau of Population, Refugees, and Migration (PRM)—a catalytic, incremental approach that will ultimately ensure existing U.S. government resources and capacities are channeled to those disordered settings where the needs of women and girls are greatest.

The \$30 million in flexible funding will be used to launch an integrated model of service delivery for women’s and girls’ health and safety. This model should be piloted in two to three priority emergency settings to demonstrate impact and generate data and lessons to inform future expansion and replication. This model should adapt, refocus, and integrate programs at USAID’s Bureau for Global Health and Office of U.S. Foreign Disaster Assistance (OFDA), PRM, and the CDC, where appropriate.

RATIONALE

The United States has unrivaled financial and programmatic capacities in maternal health, reproductive health, family planning, and GBV prevention and response. However, the U.S. government seldom marshals these extensive capacities in emergency settings, where the needs and vulnerabilities of women and girls are most severe.

Thirty-four million women and girls of reproductive age are estimated to be in emergency situations, often explicitly targeted with sexual violence as a weapon of war.⁹¹ Five million

Men walk through the rubble of a hospital that was reportedly hit by an air strike in the Syrian village of Shinan, about 30 kilometres south of Idlib in the northwestern Idlib province, on November 6, 2019. There has been a rise in attacks on health facilities and providers in conflict settings in recent years.

OMAR HAJ KADOUR/AFP VIA GETTY IMAGES



"One of my priorities as a Commissioner has been to make sure we don't lose sight of how health security threats impact families, especially how they impact women and children. When we plan for disaster, we need to make sure the needs of women and girls are prioritized from the start—not tacked on as an afterthought. We know, when crisis strikes, women often bear the brunt of the burden, as access to health care, including maternal care and family planning services, decreases. The U.S. government needs new capacities to deliver these critical services in the midst of disorder."

— U.S. Senator Patty Murray (D-WA)

of these women are pregnant and face additional health complications and challenges.⁹² Inadequate or interrupted maternal health and family planning services contribute to maternal and neonatal mortality, unintended pregnancies, and unsafe abortions. The alarmingly high risks of GBV and severely limited access to maternal health, family planning, and reproductive health services are too often overlooked in crisis settings.

A categorical shift is required for the United States to prioritize women's and girls' health and protection in emergency settings to advance resiliency and health security. Practitioners and policymakers increasingly recognize that failing to address these gaps significantly worsens the impact and trauma of crises and significantly undermines global health security. Conversely, engaging women, girls, and communities in decisionmaking and program design can help build public trust and confidence, which is sorely lacking in many health security crises around the world.

This proposed initiative would ensure that the extensive capacities of the U.S. government in the areas of maternal health, reproductive health, family planning, and GBV prevention and response are brought to bear to ensure the health and safety of women and girls in disordered settings.

Existing U.S. Government Capacity and Gaps:

The United States is the global leader in supporting humanitarian response, primarily through OFDA and PRM, which in recent years have expanded their commitment to and investments in preventing and responding to GBV, in addition to their commitment to women's health. PRM funds a range of international organizations, UN agencies, and NGOs to provide GBV prevention and response services, including through Safe from the Start, the U.S. government's flagship initiative on GBV in emergencies. OFDA leads U.S. responses to disasters overseas based on humanitarian need, focused especially on internally displaced populations, including through the deployment of DARTs. USAID's Bureau for Global Health is a global leader in supporting maternal health, reproductive health, and family planning. In April 2019, USAID announced a new \$200 million five-year program called the MOMENTUM project—Moving Integrated, Quality Maternal, Newborn, and Child Health and Family Planning and Reproductive Health Services to Scale.⁹³

These extensive capacities provide a strong foundation upon which to build a more robust, comprehensive, and impactful approach to women's and girls' health and safety needs in disordered and crisis settings.



Secretariat: The responsibility for operationalizing this model should be shared between the USAID assistant administrator for the Bureau for Democracy, Conflict and Humanitarian Assistance (DCHA), the USAID assistant administrator for the Bureau for Global Health, and the PRM assistant secretary, in close coordination with the CDC. A working group of core subject matter experts should support the secretariat in operationalizing the model, ensuring alignment of planning and investments and promoting enhanced coordination between women's and girls' health and protection across the interagency process. The agencies should report to Congress on the impact, outcomes, and lessons learned.

Where: In its initial pilot phase, the model should be implemented in two to three crisis settings, such as the DRC, South Sudan, Syria, Venezuela, or Yemen, with the intention of generating learnings to inform potential replication in other disordered settings. To determine where the model should be operationalized, careful consideration should be given to the maternal mortality rate, the percentage of unmet need for contraception, the level of services available for adolescent girls, whether U.S. agencies or partners have access to the communities in need, and impact of the crisis on U.S. health security and foreign policy interests.

Funding and Operational Requirements: Congress should authorize quick disbursing and flexible programmatic funding through USAID—including the Bureau for Global Health and USAID missions—and PRM, in close consultation with other relevant U.S. government agencies. This funding should be used in two to three priority crisis settings to spearhead this integrated service delivery model and incentivize U.S. agencies and their partners to rapidly begin execution of the program. The additional flexible funding is

just the first step. This funding will be catalytic and is intended to attract higher-level financial commitments from existing programs at USAID and PRM.

The following operational requirements should be put in place:

- Ensure that OFDA's DARTs and their implementing partners, as well as the CDC and DOD when involved, prioritize women's and girls' health and safety as part of the essential package of services offered in crisis situations.⁹⁴
- Direct PRM to dedicate increased funding for women's and girls' health and safety in refugee and forced displacement settings and to develop criteria and accountability for its UN and NGO partners to demonstrate expertise and capacity in these areas.
- Strengthen local capacity for health care providers, community outreach workers, and NGOs to provide essential health and protection services for women and girls.
- Systematically evaluate the benefits, challenges, and costs of implementation in the first two to three cases to judge the impact of the model, improve effectiveness of integrated services and the enabling environment, and capture learnings to inform whether this model should be sustained and introduced in additional crisis settings.
- Engage diplomatically at high levels to encourage other donor countries, multilateral organizations, and UN agencies to contribute and participate in this strengthened model and to hold U.S. programs and partners accountable.

ESTIMATED COST:

\$30 million per year for five years.



"The United States is the world leader in science, technology, and in global health. We need to be faster and bolder in developing new therapeutics, vaccines, and diagnostics to arrest future outbreaks. America's leadership in these areas will be essential in strengthening global health security."

— U.S. Congressman Ami Bera (D-CA-7)



7. Systematically confront two urgent technology challenges: the need for new vaccines and therapeutics and the public health communications crisis.

RECOMMENDATION

We are in the midst of a global technological revolution, which presents both opportunities and threats to global health security. In the face of emerging infectious disease and growing antimicrobial resistance, the United States should lead the global community in harnessing science and technology to save lives through the development of novel diagnostics and therapeutics. These efforts will require working with particularly dangerous pathogens. To prevent the accidental or intentional release of such pathogens, the United States should also make the small investments necessary to ensure that this research can be conducted safely and securely.

At the same time, the credibility of the scientific and medical communities is increasingly jeopardized, as

misinformation and disinformation spreads rapidly across the expanding digital domain. This poses a new and urgent global health security challenge, one that the United States should lead in addressing through a concerted effort to reclaim digital and social media as a force for good.

RATIONALE

The United States is the global leader in biotechnology capacity and innovation, a result of decades of strong market conditions and public- and private-sector investment in education, research, and development. In recent months, both Congress and the administration have demonstrated their commitment to biotechnology efforts across several fields that are central to strengthening global health security. The U.S. government should build upon these recent efforts with targeted investments in the following critical areas.

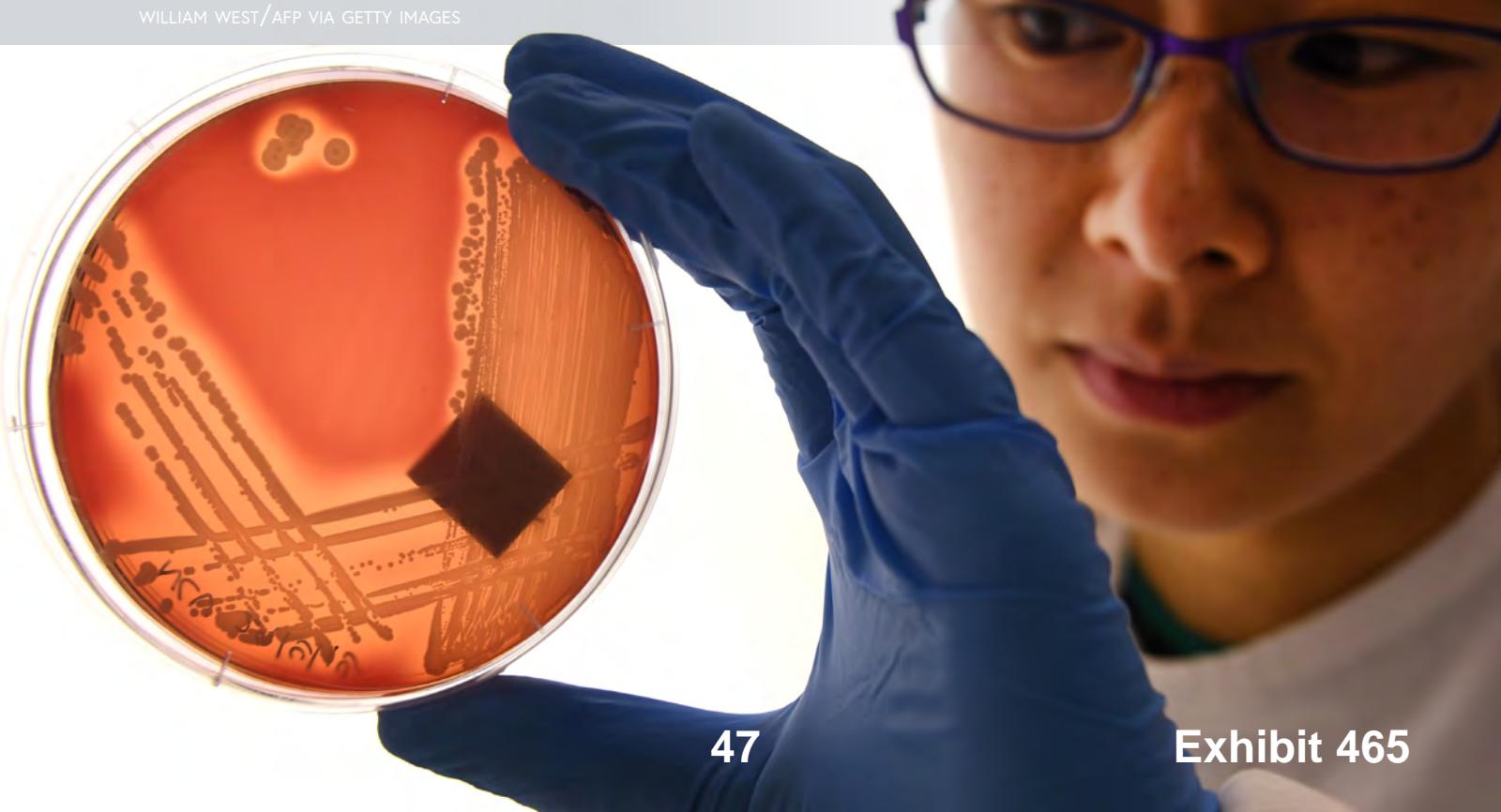
Vaccines and Therapeutics

Coalition for Epidemic Preparedness Innovations

(CEPI): As the infectious disease threat grows, the cost of investing in vaccine development remains prohibitively

*A scientist at Melbourne's Doherty Institute inspects the superbug *Staphylococcus epidermidis* on an agar plate in September 2018. Researchers at the University of Melbourne discovered three variants of the multidrug-resistant bug in samples from 10 countries.*

WILLIAM WEST/ AFP VIA GETTY IMAGES



high. An investment in CEPI will enable the United States to further this critical preparedness mission while pooling resources and risk across multiple governmental and philanthropic partners. The U.S. government should become a CEPI coalition partner with an annual investment of \$40 million. This initial investment will support CEPI's mission to accelerate the development of vaccines and platform technologies against emerging infectious diseases and ensure equitable access to these vaccines during outbreaks.

Furthermore, if the United States becomes a coalition partner, it will acquire a seat at the table early in the evolution of this promising new partnership, which will enable it to influence CEPI's decision process. A U.S. commitment to CEPI should not detract from the work of BARDA. On the contrary, in becoming a coalition partner of CEPI, the United States could better align CEPI investments with other U.S. programs and direct bilateral investments and motivate other donors, companies, and philanthropies to join the coalition.

As CEPI develops these new technologies, it will increasingly confront serious gaps in the systems and capacities needed to ensure their meaningful delivery in the case of an outbreak. Countries vulnerable to CEPI's priority diseases (e.g., MERS-CoV, Nipah virus, and Lassa virus) often lack the necessary cold chain, human resource, diagnostic, and data management capacities to effectively implement vaccination campaigns with experimental products. Creation of these capacities will likely involve partnership with Gavi, UNICEF, the WHO, product development partners, and other organizations and could have broader impacts on immunization systems beyond these priority diseases.

ESTIMATED COST

\$40 million per year for five years.

Universal Flu Vaccine: Influenza is widely recognized as today's foremost health security threat. The CDC estimates that seasonal influenza has killed between 12,000 and 79,000 Americans annually since 2010, costing the United States over \$10.4 billion in direct medical costs and \$87 billion in total economic burden every year.⁹⁵ An influenza pandemic would be even more catastrophic. A landmark 2016 study found that a moderately severe influenza pandemic could cause as many as 700,000 deaths annually and cost as much as \$570 billion globally per year.⁹⁶

The U.S. government should increase support for the creation of a universal influenza vaccine, which would save

thousands of lives every year and significantly mitigate the pandemic influenza threat. The United States is at the forefront of this scientific effort and should demonstrate leadership with investment and commitment. Experts estimate that \$200 million annually over five years is necessary to reach this crucial milestone, as was proposed in the Flu Vaccine Act.⁹⁷ This constitutes an additional \$60 million annually over current funding levels at the NIH. Funding for later stage universal flu vaccine research at BARDA should be maintained, as its efforts are crucial for bringing new flu products to the market. There should also be serious consideration given to expanding the CDC's complementary research on emerging and circulating influenza viruses, vaccine effectiveness, and the production of vaccine candidates for newer production platforms, as well as issues of access to this vaccine in low- and middle-income countries after it is developed.

ESTIMATED COST

\$60 million over current funding levels per year for five years.

Antimicrobial Resistance: To address the growing threat of AMR, Congress should fund the implementation of the National Action Plan on Combating Antibiotic Resistant Bacteria (CARB) 2020-2025. At time of writing, the funding requirements for this effort are not publicly available. The CARB 2020-2025 plan (to be released in early 2020) is expected to provide updated data and a revised plan to enable U.S. agencies to work with partner governments and multilateral partners to stem the emergence and spread of antimicrobial resistance overseas. This includes strengthening public health interventions, including infection control and surveillance and improved antibiotic use and stewardship, as well as the development of improved vaccines and novel drugs and technologies to prevent, diagnose, and treat resistant infections.

It is critically important that U.S. agencies work with partner governments to strengthen and sustain infection control in health care facilities globally such that facilities can detect, monitor, and prevent the transmission of the most urgent antibiotic-resistant bacterial threats. In addition, by supporting countries to build surveillance systems that can collect and integrate AMR data from the medical, veterinary, agricultural, and environmental sectors, the United States can strengthen its own capacity to detect and prevent the spread of resistance. Additional technical support in this field will also enable partner governments to enact and enforce rules limiting over-the-counter availability of antibiotics and overprescribing,



"The reason why so few antibiotics are being developed is simple – the market is broken. In recent months, lawmakers on both sides of the aisle have come together to introduce important policies designed to spur the development of new antibiotics. However, to protect the American people from resistant superbugs, bold action is needed from Congress and the Administration to stimulate innovation and produce new antimicrobials that patients and society can count on."

— Jim Greenwood, *Biotechnology Innovation Organization*

raising standards in those countries with the least stringent standards and highest burden of drug-resistant infections.

When developing new antibiotics, the private sector remains the primary actor in bringing new drugs to market. However, the lack of a predictable, strong market for new antibiotics has caused private-sector investment to drop significantly, with the few pharmaceutical companies and biotechnology firms that remain engaged struggling to remain viable. Amid the unresolved furor over drug pricing, policymakers and the public at large may be understandably hesitant to support giving taxpayer dollars to incentivize drug companies. Nevertheless, government intervention is needed to create a robust and sustainable antimicrobial research and development ecosystem, such that companies are rewarded for the development of novel antimicrobial products and developers get a certain return.

Congress and the administration should redouble their efforts to formulate pull-incentive packages that guarantee drug developers a certain return for the development of novel antimicrobial products that address the greatest public health need. Such incentive packages are likely to win bipartisan support and should include robust stewardship and surveillance requirements, requiring developers to ensure the responsible use and accessibility of the antimicrobial product both for Americans and for patients around the globe. The DISARM Act of 2019 is a welcome step toward a sustainable marketplace that supports the antibiotic research and development pipeline while allowing health care providers to use novel antibiotics when needed.⁹⁸

Digital Disinformation

VACCINE CONFIDENCE

The crisis in confidence in science, medicine, and vaccines is an emergent and intensifying health security threat that the United States is not yet equipped to address.

The White House should establish a new capacity under the auspices of the NSC directorate for global health security and biodefense that can lead collaboration across agencies and sectors to address this fundamentally multisectoral issue. This should include a comprehensive assessment of U.S. government capacities to monitor and counter online disinformation and misinformation around science and medicine. The focal person for this effort should engage with social media platforms and technology companies, independent media, biopharmaceutical companies, medical providers, and cybersecurity experts to inform policy formulation on this pressing issue.

The U.S. government should also establish an expanded, integrated, and sustained effort at the CDC to strengthen vaccine confidence and demand both in the United States and abroad. This should integrate all relevant capacities across the CDC and should include:

- A strategic communications initiative that is informed by behavioral psychology research to understand the determinants of local group belief systems and that provides consistent, science-based information to all audiences, both domestic and global, to



"Research and biotechnology development are critical for identifying and preparing for future infectious disease outbreaks. It is equally important that the U.S. and countries around the world bolster mechanisms to identify and reduce biological risks associated with advances in technology. Congress should allocate additional resources for biosecurity and biosafety innovation."

— *Laura S. H. Holgate, Ambassador (Ret.), Nuclear Threat Initiative*

counter misinformation and disinformation across multiple media platforms;

- Expanded research and survey work with global and university partners on the behavioral and social drivers of public trust and vaccine confidence and the acceptability and accessibility of services, including a U.S. Government Accountability Office (GAO) report on public attitudes toward vaccinations;
- An expanded program for the provision of technical expertise to partner governments, and U.S. states and municipalities, to generate vaccine demand;
- Expanded efforts to identify communities with low vaccination coverage and at high risk of outbreaks related to vaccine-preventable diseases, to conduct targeted and culturally and linguistically appropriate communications campaigns in those communities, and to improve vaccination rates in such communities through improved surveillance, vaccination interventions and campaigns, and research initiatives; and
- Expanded support for the Global Demand Hub, an established international platform that convenes public health officials, international organizations (including the WHO, UNICEF, and Gavi), social media firms, and civil society to research, incentivize, and coordinate vaccine demand work.

Experts estimate a minimum of \$50 million in additional annual funding will be required to support this initiative over a five-year period. This increase to CDC's multi-billion-dollar annual funding for immunization could potentially be pivotal in mobilizing multiple interests

behind renewing and stabilizing broad popular support for vaccines at home and abroad.⁹⁹ This proposal is broadly consistent with what is outlined in the bipartisan VAC-CINES Act of 2019 and the VIP Act of 2019, as well as Senate action through the Lower Health Care Costs Act of 2019.^{100,101,102}

ESTIMATED COST:

\$50 million per year for five years.

Biosafety and Biosecurity

Much of the funding called for in this section relates to research on especially dangerous pathogens, including pathogens with pandemic potential, and often involves the isolation, growth, and manipulation of dangerous viruses. A small fraction of the funds spent on researching dangerous pathogens should be set aside to ensure that this research is conducted safely and securely to prevent the accidental and intentional release of dangerous pathogens.

This will require investments in biosafety (to prevent the accidental exposure of people, animals, and the environment to dangerous microbes) and biosecurity (to prevent the deliberate exposure of people, animals, and the environment to dangerous microbes).^{103,104}

Biosafety: Congress should allocate funding to the National Institute for Occupational Safety and Health (NIOSH) for the empirical study of safety in biological laboratories.¹⁰⁵ This funding will support the research needed to upgrade biosafety in the age of synthetic biology and escalating risk. Experts estimate that an initial phase of research should be funded at \$10 million a year.¹⁰⁶

Biosecurity: Congress should allocate funding to HHS to conduct comprehensive biosecurity oversight, in close coordination with other departments and agencies. This should include risk mitigation measures associated with life sciences dual-use research and overseeing innovations in biosecurity and microbial forensics that can reduce biological risks associated with advances in technology and better detect emerging, unusual, or engineered pathogens.

The U.S. government should expand DTRA's Biological Threat Reduction Program (BTRP) authorities to increase flexibility in detecting and countering the emergence of novel, highly communicable diseases, such as multidrug-resistant tuberculosis and artemisinin-resistant malaria.¹⁰⁷ The U.S. government should expand DTRA's geographic authorities to operate in all continents where health security threats exist, including South America. Furthermore, support for military overseas infectious disease research laboratories should be sustained. DOD biological research and development programs often focus on diseases not studied in other venues and result in medical countermeasures that would otherwise be delayed or not developed at all.¹⁰⁸

ESTIMATED COST:

Biosafety: \$10 million per year for five years.

Biosecurity: \$10 million per year for five years.

Time to Act

We opened the Commission's report sounding the alarm that the U.S. government is caught in a cycle of crisis and complacency, that the American people are far from safe, and that U.S. policymakers need to think anew.

The “microbial sky” under which the United States and the rest of the world live today is increasingly crowded with health security threats, yet preparedness lags at home and abroad. At the same time, the world is increasingly disordered, and the most dangerous and inaccessible areas are also where many dangerous outbreaks arise. These realities should make anyone nervous and uncomfortable.

Over the course of deliberating on these complex challenges and the actions required to defend U.S. national interests, the Commission has settled on what we believe are cost-effective, proven, commonsense solutions that can draw support across the political divide. Now is the time for Congress and the administration to move these actions forward. It is a moment to hold ourselves and our government to greater account, to insist upon White House leadership, and to demand a higher level of rigor and discipline in the use of scarce resources. The U.S. government cannot afford waste, redundancy, or mistargeted investments.

The changes we advocate do come at a price. There is no denying that. But it is a smart investment when set against the staggering costs of inaction. We are calling for targeted investments in country partnerships, in quick response capacities, and in the U.S. government’s ability to operate in insecure, disordered settings. We are calling for smart investments that will help accelerate new technologies and focus U.S. energies and the energies of others on the public health communications crisis in the age of misinformation, social media, and distrust.

The steps we have laid out are the foundation of the Commission’s proposed U.S. doctrine of continuous prevention, protection, and resilience. If the U.S. government acts strategically to advance this doctrine, it can, once and for all, break the cycle of crisis and complacency and put the United States’ global health security approach on a sound footing for the future.

Appendix I

Illustrative Costing for Recommended Programs and Initiatives

This appendix captures proposed, current, and historical funding levels (when available) for the recommended programs and initiatives. Figures are presented in millions USD. We have calculated the incremental difference, or additional cost beyond current funding levels, to be approximately \$905 million.^D Unless otherwise noted in the text, all recommended funding levels are annual investments over five years. It is recommended that funding levels be reassessed after five years. While the proposed funding levels represent expert estimates, additional work may be required to cost certain expanded initiatives and new program proposals.

D. The estimated incremental difference is not reflective of FY 2019 levels for new program proposals or vaccine confidence, as those numbers are unavailable.

GLOBAL HEALTH SECURITY AGENDA ¹												
Executive Agency	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	Proposed	Difference
USAID (NON-ADD)	\$201	\$48	\$58	\$55	\$73	\$385	\$218	\$73	\$173	\$138	\$173	\$35
CDC (NON-ADD)	\$62	\$51	\$56	\$54	\$63	\$652	\$55	\$58	\$108	\$108	\$208	\$100

1. Sources: Kaiser Family Foundation (KFF) analysis of appropriations bills and Congressional budget requests; Watson et al., "Federal Funding for Health Security in FY2019," *Health Security* 16, no. 5 (October 2018): <https://doi.org/10.1089/hs.2018.0077>. Sources of proposed funding levels include the Global Health Council's Global Health Security Roundtable and the Global Health Security Agenda Consortium.

PANDEMIC PREPAREDNESS CHALLENGE			
	FY19	Proposed	Difference
PANDEMIC PREPAREDNESS CHALLENGE		\$30 ¹	\$30

1. Expert estimate of the annual investment over five years required by the United States to leverage donor funding necessary to launch a five-year, \$750 million Pandemic Preparedness Challenge.

CONTINGENCY FUNDS

EXISTING FUND	FY17	FY18	FY19	PROPOSED	DIFFERENCE
CDC INFECTIOUS DISEASES RAPID RESPONSE RESERVE FUND			\$50 ¹	\$250 ²	\$200
USAID EMERGENCY RESERVE FUND	\$70 ³	\$35 ⁴	\$2 ⁵	\$250 ⁶	\$248
WHO CONTINGENCY FUND FOR EMERGENCIES				\$25 ⁷	\$25

1. "FY2019 Operating Plan," CDC, accessed June 2019, <https://www.cdc.gov/budget/documents/fy2019/fy-2019-cdc-operating-plan.pdf>.
2. Expert estimate of the minimum funding levels for contingency funds at the CDC to support rapid response. Sources include the Global Health Council's Global Health Security Roundtable. These contingency fund levels are inclusive of the \$20 million in contingency funds for emergency immunization activities recommended in Recommendation 6.
3. "State, Foreign Operations, and Related Programs Appropriations Bill, 2017 Omnibus Agreement Summary," U.S. Senate Committee on Appropriations, accessed June 2019, <https://www.appropriations.senate.gov/imo/media/doc/FY17%20State%20Foreign%20Operations%20Conference%20Agreement%20Summary%20-%20Final.pdf>.
4. "President Signs FY18 Omnibus Bill," KFF, March 22, 2018, <https://www.kff.org/news-summary/congress-releases-fy18-omnibus/>.
5. "FY19 Conference Agreement Released, Includes State & Foreign Operations (SFOPs) Funding," KFF, February 14, 2019, <https://www.kff.org/news-summary/fy19-conference-agreement-released-includes-state-foreign-operations-sfops-funding/>.
6. Expert estimate of the minimum funding levels for contingency funds at USAID to support rapid response. Sources include the Global Health Council's Global Health Security Roundtable. These contingency fund levels are inclusive of the \$20 million in contingency funds for emergency immunization activities recommended in Recommendation 6.
7. Expert estimate of appropriate U.S. government contribution to the WHO CFE based on contributions of similar donor countries, including Japan (\$22 million contribution in 2019), Germany (\$8 million in 2019), and the United Kingdom (\$5 million in 2019). See: "Contingency Fund for Emergencies (CFE) contributions and allocations," WHO, accessed June 2019, <https://www.who.int/emergencies/funding/contingency-fund/allocations/en/>.

GLOBAL HEALTH CRISES RESPONSE CORPS

Focus area	FY19	Proposed	Difference
GLOBAL HEALTH CRISES RESPONSE CORPS		\$50 ¹	\$50
SUPPORT TO NATIONAL PARTNERS	\$47.5	\$83.5 ²	\$36
PHEM (CDC)	\$1.5 ³	\$2.5 ⁴	\$1
FETP (CDC)	\$41 ⁵	\$71 ⁶	\$30
NPHI (CDC)	\$5 ⁷	\$10 ⁸	\$5

1. Expert estimate of the cost of a pilot program is based on estimated costs of: (1) personnel; (2) training costs, including existing agency training opportunities; and (3) deployment-related costs, including first aid supplies, food and water, lodging, travel (commercial flights, not designated transport), emergency communication measures, and personal security measures. Estimate takes into account original FY 2010 non-supplemental appropriation for the U.S. Civilian Response Corps, adjusted for the size and scope of this proposed Corps.
2. Experts estimate that additional investment in these three programs will help to ensure greater national capacity in outbreak detection and management.
3. U.S. Centers for Disease Control and Prevention, "FY2019 Operating Plan."
4. Expert estimate of the additional annual funding required to expand these programs to include a focus on operating in disordered environments.
5. U.S. Centers for Disease Control and Prevention, "FY2019 Operating Plan."
6. Expert estimate of the additional annual funding required to expand these programs to include a focus on operating in disordered environments.
7. U.S. Centers for Disease Control and Prevention, "FY2019 Operating Plan."
8. Expert estimate of the additional annual funding required to expand these programs to include a focus on operating in disordered environments.

STRENGTHEN SERVICE DELIVERY IN DISORDERED SETTINGS

Focus area	FY19	Proposed	Difference
IMMUNIZATIONS		\$6	\$6
STRENGTHEN DATA		\$5 ¹	\$5
TRAINING COMMUNITY WORKERS		\$1 ²	\$1
WOMEN AND GIRLS		\$30 ³	\$30

1. Expert estimate of the cost of a pilot program monitoring 20 countries is based on consultation on the FEWS NET program and estimated costs for: (1) personnel; (2) database conceptualization, development, testing, and maintenance; and (3) website development, maintenance, and hosting.

2. Expert estimate of the cost of training for 150 trainees is based on estimated average cost of \$6,500 per trainee for FETP-Frontline 3-month training for local public health staff.

3. Expert estimate of pilot program costs in two to three humanitarian crises, considering: (1) estimates of the number of affected women and girls in these crises from OCHA and UNHCR; (2) costs of assumed 20 percent uptake of family planning services, based on cost per couple-year of protection; (3) cost of assumed 20 percent uptake in maternal health care, based on average cost per pregnancy; (4) cost of GBV care, based on assumed 20 percent uptake; and (5) estimated cost of health care worker and community outreach worker capacity building.

CONFRONTING TECHNOLOGY CHALLENGES

Focus area	FY19	Proposed	Difference
VACCINES		\$290	\$125
CEPI		\$40 ¹	\$40
UNIVERSAL INFLUENZA VACCINE (NIH/NIAID)	\$140 ²	\$200 ³	\$60
VACCINE CONFIDENCE (CDC)		\$50 ⁴	\$25
BIOSAFETY (CDC/NIOSH)		\$10 ⁵	\$10
BIOSECURITY (HHS)		\$10 ⁶	\$10

1. Expert estimate for initial annual funding level.

2. "Operating Plan for FY2019," National Institutes of Health, accessed June 2019, https://www.hhs.gov/sites/default/files/FY%202019%20NIH%20Operating%20Plan_0.pdf

3. U.S. Congress, Senate, Flu Vaccine Act, S.570, 116th Cong., 1st sess., introduced in Senate February 26, 2019, <https://www.congress.gov/116/bills/s570/BILLS-116s570is.pdf>.

4. Expert estimate of the additional annual funding required to expand, sustain, and integrate existing CDC programs and initiatives.

5. Expert estimate for minimum annual funding levels to support basic biosafety research. In comparison, the budgets of the Chemical Safety Board and the Nuclear Regulatory Commission each exceed \$1 billion annually. For more detailed recommendations on this issue, refer to Rocco Casagrande, "Federal Funding for Biosafety Research is Critically Needed," CSIS, Commentary, August 6, 2019, <https://healthsecurity.csis.org/articles/federal-funding-for-biosafety-research-is-critically-needed/>.

6. Expert estimate for initial annual funding level.

Appendix II

Congressional Authorities and Oversight of U.S. Government Efforts to Advance Global Health Security

As described in White House Executive Order 13747 on “Advancing the Global Health Security Agenda to Achieve a World Safe and Secure from Infectious Disease Threats” and the new Global Health Security Strategy, the U.S. government’s role in global health security is a whole-of-government enterprise.^{109, 110} The executive order (EO) and the strategy lay out the roles and responsibilities of the Executive Office of the President (EOP); eight Cabinet-level departments (including the Departments of State, Defense (DOD), Health and Human Services (HHS), Agriculture, Homeland Security, Treasury, Interior, and Justice); and eight sub-Cabinet agencies (including the Centers for Disease Control and Prevention (CDC), U.S. Agency for International Development (USAID), National Institutes of Health (NIH), Food and Drug Administration (FDA) and Environmental Protection Agency (EPA)). As a result, multiple Congressional authorizing and appropriations committees have jurisdiction over various aspects of this agenda, underscoring the essential interplay between international and domestic efforts to protect Americans’ health and safety.

The Commission’s recommendations to strengthen U.S. government support for global health security focus on a subset of departments and agencies for priority action. This list includes the Department of State, including USAID; HHS, including the CDC and the Biomedical Advanced Research and Development Authority (BARDA); the DOD, including the Defense Threat Reduction Agency (DTRA); and the Department of the Treasury. Below is a summary of the key Congressional committees with oversight of these agencies and their relevant programs. Note that most recent global health security-related authorizations have occurred via appropriations legislation, including through the five-year Ebola Emergency Supplemental spending bill which expired at the end of FY 2019.

Health and Human Services

AUTHORIZING COMMITTEES

- Senate: Health, Education, Labor and Pensions (HELP) Committee, Subcommittee on Primary Health and Retirement Security
- House: Energy and Commerce Committee, Subcommittee on Health

APPROPRIATIONS COMMITTEES

- Senate and House: Labor, Health and Human Services, Education, and Related Agencies

These committees have oversight and jurisdiction over the HHS agencies, institutes, and programs relevant for global health security, notably the activities of the CDC, FDA, NIH, and BARDA. Relevant authorizing legislation includes the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAI), which authorizes certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response, including advancement of medical countermeasures.

President Trump signed PAHPAI into law in June 2019.¹¹¹ The International Health Research Act of 1960 provides for international cooperation in health research, research training, and planning and authorizes the HHS secretary to enter into cooperative agreements for biomedical and health activities.

The primary relevant funding accounts or line items for global health security include: the CDC’s Division of Global Health Protection (including the Global Disease Detection Program and the Field Epidemiology Training Program (FETP)), the Epidemic Intelligence Service, Emerging and Zoonotic Infectious Diseases, Public Health Preparedness and Response, Immunization and Respiratory Diseases, and the Infectious Diseases Rapid Response Reserve Fund, which was established by Congress in the FY 2019 appropriations bill; HHS’s Office of Global Affairs; BARDA’s emerging infectious diseases (EID) program under the Office of the Assistant Secretary for Preparedness and Response (ASPR); and NIH’s Fogarty International Center.

Department of State and USAID

AUTHORIZING COMMITTEES

- Senate: Committee on Foreign Relations, Subcommittee on Africa and Global Health Policy
- House: Committee on Foreign Affairs (HFAC), Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations

APPROPRIATIONS COMMITTEES

- Senate and House: State, Foreign Operations, and Related Programs

These committees have jurisdiction over all Department of State and USAID operations and assistance programs,

including global health related programs. Relevant authorizing legislation includes the Department of State Authorities Act (last passed in 2017) and the Foreign Assistance Act of 1961. As there have not been regular authorization bills (with the exception of the PEPFAR authorization, whose extension was last authorized in 2018), most programs are authorized via appropriations. In the 116th Congress, the Global Health Security Act was introduced to codify the U.S. commitment to the Global Health Security Agenda and designate permanent leadership for coordinating the interagency response to a global health security emergency. The bill was referred to the HFAC as well as to Armed Services and the Permanent Select Committee on Intelligence.

The primary relevant accounts or line items for global health security include: the USAID Emerging Pandemic Threats Program and its PREDICT project and the Emergency Reserve Fund; the Department of State's Bureau of Oceans and International Environmental and Scientific Affairs Office of International Health and Biodefense and Bureau of International Security and Nonproliferation Biosecurity Engagement Program; and the U.S. contributions to the World Bank's International Development Association (IDA) and the World Health Organization (WHO).

Department of Defense

AUTHORIZING COMMITTEES

- Senate and House: Armed Services Committee

APPROPRIATIONS COMMITTEES

- Senate and House: Defense

These committees have oversight and jurisdiction over all DOD-supported global health security programs. The annual National Defense Authorization Act (NDAA) is the principal authorizing legislation. The primary relevant funding accounts or line items for global health security include: the Defense Threat Reduction Agency (DTRA) and its Cooperative Threat Reduction Directorate's Cooperative Biological Engagement Program (CBEP); the Armed Forces Health Surveillance Branch Global Emerging Infections Surveillance and Response Program; the Army Medical Research and Development Command's Military Infectious Diseases Research Program; the Naval Medical Research Center and Naval Research Laboratory; the Walter Reed Army Institute of Research; and the Defense Advanced Research Projects Agency (DARPA). The geographic combatant commands also engage with their international military partners on health security cooperation.

Treasury

AUTHORIZING COMMITTEES

- Senate: Committee on Banking, Housing, and Urban Affairs, Subcommittee on National Security and International Trade and Finance
- House: Committee on Financial Services, Subcommittee on National Security, International Development and Monetary Policy

APPROPRIATIONS COMMITTEES

- Senate and House: State, Foreign Operations, and Related Programs

These committees have oversight and jurisdiction over U.S. membership in, and financial support for, the World Bank's IDA and International Bank for Reconstruction and Development (IBRD) and other multilateral development banks (MDBs) and international financial institutions. Relevant recent authorization bills include the World Bank Accountability Act, introduced in the House in 2017 to authorize IDA appropriations. However, as with other Department of State and Foreign Operations-funded programs, most authorizations have occurred through the annual appropriations bills.

Appendix III

Glossary of Key Terms

ANTIMICROBIAL RESISTANCE (AMR)¹¹²

Many common infections are becoming resistant to the antimicrobial medicines used to treat them, resulting in longer illnesses and more deaths. Antimicrobial resistant microbes are found in people, animals, food, and the environment. They can spread between people and animals, including from food of animal origin, and from person-to-person. Poor infection control, inadequate sanitary conditions, and inappropriate food-handling encourage the spread of AMR. Misuse and overuse of antimicrobials is also accelerating AMR. Many common infections are becoming resistant to the antimicrobial medicines used to treat them, resulting in longer illnesses and more deaths, and not enough new antimicrobial drugs, especially antibiotics, are being developed to replace older and increasingly ineffective ones. AMR also increases the cost of health care, with lengthier stays in hospitals and more intensive care required. In 2016, the UN General Assembly issued a declaration calling for global action on AMR.¹¹³

BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY (BARDA)¹¹⁴

BARDA was established in 2006 through the Pandemic and All-Hazards Preparedness Act (PAHPA) and reports to the Office of the Assistant Secretary for Preparedness and Response (ASPR) in the Department of Health and Human Services (HHS). BARDA is responsible for the development and procurement of medical countermeasures (MCMs) to enhance the capability of the U.S. government to guard against a broad array of public health threats, including chemical, biological, nuclear, and radiological threats, as well as pandemic influenza and emerging diseases such as Ebola and Zika. BARDA supports the transition of medical countermeasures such as vaccines, therapeutics, drugs, and diagnostics from research through advanced development toward consideration for approval by the Food and Drug Administration (FDA) and inclusion into the Strategic National Stockpile.

BIOLOGICAL THREAT REDUCTION PROGRAM (BTRP)¹¹⁵

The Defense Threat Reduction Agency's (DTRA) Cooperative Threat Reduction (CTR) Directorate prevents the proliferation or use of weapons of mass destruction (WMD) by working with partner nations to secure, eliminate, detect, and interdict WMD-related systems and materials. The CTR Biological Threat Reduction Program (BTRP) addresses the

biological threat aspect of this threat reduction mission. BTRP facilitates elimination, security, detection, and surveillance of especially dangerous pathogens.

COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS (CEPI)¹¹⁶

Launched at the World Economic Forum in January 2017, CEPI is a global partnership of public, private, philanthropic, and civil society organizations designed to accelerate the development of vaccines against emerging infectious diseases and to support equitable delivery of those vaccines in response to epidemics. CEPI focuses on vaccine development, licensure, and manufacturing for a target set of pathogens (currently MERS-CoV, Lassa, Nipah, Rift Valley fever, and Chikungunya) and is promoting the development of platform technologies that can be adapted to develop countermeasures to a future unknown pathogen with pandemic potential, "Disease X." As of April 2019, CEPI had secured \$750 million toward its \$1 billion funding target, with support from Australia, the Bill & Melinda Gates Foundation, Canada, Germany, Japan, Norway, and Wellcome Trust. The United States does not currently contribute to CEPI.

DISASTER ASSISTANCE RESPONSE TEAM (DART)¹¹⁷

The USAID Office of U.S. Foreign Disaster Assistance (OFDA) sends a DART to crisis-affected areas when required by the size and severity of a disaster. DARTs are comprised of humanitarian experts and technical advisers and are deployable within hours of an emergency. They work in cooperation with partners on the ground to assess and respond to a crisis situation. DARTs work overseas but are managed by a Response Management Team (RMT) based in Washington, D.C. RMTs work with other U.S. government agencies to plan and coordinate the response so that the DART can focus on providing support on the ground.

DEFENSE ADVANCED RESEARCH PROJECTS AGENCY (DARPA)¹¹⁸

DARPA's mission is to make pivotal investments in breakthrough technologies for national security. DARPA's research portfolio is managed by six technical offices charged with developing breakthrough technologies. One of those offices, the Biological Technologies Office (BTO), develops capabilities that embrace the unique properties of biology—adaptation, replication, complexity—and applies those features to revolutionize how the United States

defends the homeland and prepares and protects its soldiers, sailors, airmen, and marines.¹¹⁹ The BTO helps the Department of Defense (DOD) to counter novel forms of bioterrorism, deploy innovative biological countermeasures to protect U.S. forces, and accelerate warfighter readiness and overmatch to confront adversary threats.

DEFENSE THREAT REDUCTION AGENCY (DTRA)¹²⁰

Created in 1998 by combining several DOD entities, DTRA facilitates and expedites research and development into some of the most complex, deadly, and urgent threats facing the United States and the rest of the world. DTRA's mission is to enable the U.S. government to counter the threats posed by the full spectrum of WMD, including chemical, biological, radiological, nuclear, and high-yield explosives; counter the threats posed by the growing and evolving categories of improvised threats, such as improvised explosive devices (IEDs), car bombs, and weaponized consumer drones; and ensure that the U.S. military maintains a safe, secure, effective, and credible nuclear weapons deterrent.

FIELD EPIDEMIOLOGY TRAINING PROGRAM (FETP)¹²¹

The U.S. Centers for Disease Control and Prevention (CDC) established the first FETP in 1980 to help epidemiologists in developing countries gain the necessary skills to collect, analyze, and interpret disease information. By training disease detectives in their own countries, the FETP helps meet the global health security goal of establishing a trained public health workforce that helps stop outbreaks at their source. There are more than 10,000 FETP graduates from 65 countries trained in disease detection and response.

GAVI, THE VACCINE ALLIANCE¹²²

Created in 2000, Gavi, the Vaccine Alliance is an international public-private partnership with the mission of improving access to new and underused vaccines for children in lower-income countries. Gavi's partnership model combines the technical expertise of the development community with the business knowledge of the private sector. Gavi partners include the WHO, UNICEF, the World Bank, the Bill & Melinda Gates Foundation, civil society organizations, private-sector companies, donor and implementing country governments, and research agencies. Gavi pools demand from low-income countries and works with vaccine manufacturers to bring down prices. While donors provide long-term, predictable financing support to Gavi's efforts, all Gavi-supported countries pay a share of the vaccine cost, and that share increases as the country's income grows. Gavi's current strategy aims to reach 300

million children between 2016 and 2020, saving five to six million lives in the long term.

GLOBAL HEALTH SECURITY¹²³

Global health security refers to the capacity to prepare for, detect, and respond to infectious disease threats and reduce or prevent their spread across borders. At the core of global health security are strong health systems with the resources and trained personnel needed to identify threats, respond quickly, and prevent the spread of infectious diseases. Key capacities include public health capabilities such as laboratory and digital information networks, supply chains, and frontline health workers.

GLOBAL HEALTH SECURITY AGENDA (GHSA)¹²⁴

Launched in February 2014, the GHSA is a growing partnership comprised of more than 65 nations, international organizations, and nongovernmental stakeholders to help build countries' capacity to create a world safe and secure from infectious disease threats and elevate health security as a national and global priority. Through a set of "Action Packages," GHSA member countries collaborate toward specific objectives and targets. This international engagement includes ministries of agriculture, defense, health, development, and others, representing a whole-of-government approach. The United States has reaffirmed its commitment to the GHSA through 2024, in support of the GHSA 2024 Framework.¹²⁵ The U.S. government provides support for capacity building for 17 priority GHSA partner countries and sits on the GHSA Steering Committee.

GLOBAL HEALTH SECURITY STRATEGY (GHSS)¹²⁶

Issued by the White House in May 2019 in response to a request from Congress in the FY 2018 omnibus appropriations bill, the GHSS outlines the U.S. government approach to strengthening global health security, including accelerating the capabilities of targeted countries to prevent, detect, and respond to infectious disease outbreaks. Together with the National Security Strategy, the National Biodefense Strategy, and the executive order on "Advancing the Global Health Security Agenda to Achieve a World Safe and Secure from Infectious Disease Threats," the GHSS delineates the roles and responsibilities of executive branch agencies in protecting the United States and its partners abroad from infectious disease threats by working with other nations, international organizations, and nongovernmental stakeholders.

GRAY ZONE¹²⁷

Recent analyses of challenges to U.S. security have identified the gray zone, a phenomenon in which actors across the globe engage in malign activities that fall somewhere in the

space between routine statecraft and open warfare. These gray zone approaches and incidents create dilemmas for the United States and its security interests but largely side-step thresholds for military escalation.

GLOBAL RAPID RESPONSE TEAM (GLOBAL RRT)¹²⁸

The CDC Global Rapid Response Team can be deployed within the United States and overseas to respond to global public health concerns. The Global RRT is comprised of public health experts and can be deployed to provide field-based logistics, communications, management, and operations support in a public health emergency. The Global RRT can also provide long-term staffing for international emergency responses both in the field and at CDC headquarters in Atlanta, Georgia.

INTERNATIONAL DEVELOPMENT ASSOCIATION CRISIS RESPONSE WINDOW (IDA - CRW)¹²⁹

IDA is the part of the World Bank that funds the world's poorest countries. Overseen by 173 shareholder nations, with the United States as the largest shareholder, IDA is one of the largest sources of assistance for the world's 75 poorest countries, 39 of which are in Africa, and is the single largest source of donor funds for basic social services and poverty reduction efforts in these countries.¹³⁰ IDA provides loans (called "credits") and grants to boost economic growth, reduce inequalities, and improve people's living conditions. The CRW was established in 2011 to help IDA countries access additional resources to respond to severe economic crises and major natural disasters and return to their long-term development paths. In 2015, the CRW eligibility criteria were expanded to include public health emergencies and epidemics.

INTERNATIONAL HEALTH REGULATIONS (IHR)¹³¹

A legally binding instrument of international law adopted by the World Health Assembly in 2005 in the wake of the SARS pandemic, the purpose of the IHR is to provide a universal framework for international public health emergency preparedness and response. The IHR aim to control the international spread of disease in ways that are commensurate with public health risks and avoid unnecessary interference with international traffic and trade. The IHR also guide the strengthening of public health surveillance and response capacities globally and require countries to report specific disease outbreaks and any event that may pose a risk to international public health. The WHO has few effective means of enforcing the IHR; however, the Joint External Evaluation (JEE) process launched in the wake of the 2014-2016 Ebola epidemic in West Africa has helped shine a light on the need

for countries to strengthen their IHR compliance.

JOINT EXTERNAL EVALUATIONS (JEEs)¹³²

The JEEs are country-owned, voluntary, collaborative, multisectoral assessments of a country's core capacity to prevent, detect, and rapidly respond to public health risks, whether naturally occurring or due to deliberate or accidental events. The JEE process is managed by the WHO and consists of a national self-assessment and an external evaluation team with experts from all relevant sectors, such as human and animal health, food safety, agriculture, defense, and public safety. JEE results are published on the WHO website.¹³³ At time of writing, over 100 countries, including the United States, had completed JEEs.¹³⁴

NATIONAL BIODEFENSE STRATEGY¹³⁵

The National Biodefense Strategy, mandated by Congress and released on September 18, 2018, sets the course for the U.S. government to effectively counter threats from naturally occurring, accidental, and deliberate biological events. The strategy orchestrates, for the first time, a single coordinated effort across the U.S. government to assess, prevent, detect, prepare for, respond to, and recover from biological threats. The accompanying National Security Presidential Memorandum directs the secretary of Health and Human Services to serve as the federal lead in coordination and implementation of the strategy and establishes a cabinet-level Biodefense Steering Committee.

NATIONAL PUBLIC HEALTH INSTITUTES (NPHIS)¹³⁶

NPHIs provide leadership and coordination for public health at the national level. NPHIs consolidate in-country public health functions, bringing together data and expertise while coordinating efforts across sectors. The CDC provides technical expertise in support of NPHIs' development, targeted to fit countries' public health priorities.

PANDEMIC AND ALL-HAZARDS PREPAREDNESS AND ADVANCING INNOVATION ACT (PAHPAI)

After the September 11, 2001 attacks and the 2001 anthrax attacks, Congress mandated a dedicated effort to develop and stockpile drugs, vaccines, and diagnostics needed to protect the American people from chemical, biological, radiological, nuclear (CBRN), and pandemic threats. The first 2006 Pandemic and All-Hazards Preparedness Act (PAHPA) created the position of the assistant secretary for Preparedness and Response (ASPR) to lead the government's response to national health emergencies.¹³⁷ The bill also created BARDA to provide industry partners with funding and technical assistance in the advanced research and development of medical countermeasures. Key federal

programs reauthorized and funded every five years through the PAHPA legislation include the BioShield Special Reserve Fund (SRF), BARDA, and the Strategic National Stockpile (SNS), which helps strengthen the pipeline and stockpile of medical countermeasures vital for national safety and defense. PAHPAI was signed into law by President Trump in June 2019 and reauthorized PAHPA.¹³⁸

PANDEMIC EMERGENCY FINANCING FACILITY (PEF)¹³⁹

The PEF was established by the World Bank in 2016 to be a quick-disbursing financing mechanism that provides a surge of funds to enable a rapid response to a large-scale disease outbreak. Eligible countries can receive timely, predictable, and coordinated surge financing if they are affected by an outbreak that meets the PEF's activation criteria. The PEF is the first-ever insurance mechanism for pandemic risk, offering coverage to all low-income countries eligible for IDA financing.

PUBLIC HEALTH EMERGENCY OF INTERNATIONAL CONCERN (PHEIC)¹⁴⁰

Some serious international public health crises may be designated PHEICs. A PHEIC is defined under the IHR (2005) as "an extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other States through the international spread of disease; and (ii) to potentially require a coordinated international response."¹⁴¹ The designation of a PHEIC implies that such situations are serious, unusual, or unexpected, carry implications for public health beyond the affected country's national border, and may require immediate international action. The WHO director-general makes the final determination on designating PHEICs based on technical advice from the IHR Emergency Committee.

PUBLIC HEALTH EMERGENCY MANAGEMENT (PHEM) FELLOWSHIP¹⁴²

Established in 2013, the CDC's PHEM Fellowship program builds capacity among members of the international public health community through standardized training, mentorship, and technical assistance in public health emergency management functions and operations. The program was established in 2013 and is conducted twice a year at the CDC in Atlanta. It targets mid-career professionals who work in public health preparedness and response in countries who have signed on to the IHR.

PULL INCENTIVES¹⁴³

Pull incentives reward the successful development of medical countermeasures by increasing or ensuring future revenue and market viability. Pull incentives can take many

forms, including advanced market commitments, higher reimbursement, priority review vouchers, market exclusivity rewards, market entry rewards, patent extensions, data protection, and liability protection.

U.S. PUBLIC HEALTH SERVICE¹⁴⁴

The U.S. Public Health Service is a division of HHS. Its mission is to protect, promote, and advance the health and safety of the United States. It is an elite team of over 6,500 health professionals, including physicians, dentists, nurses, therapists, pharmacists, engineers, dieticians, veterinarians, environmental health specialists, and scientists. Members of the U.S. Public Health Service serve in public health and clinical roles within the nation's federal government departments and agencies, supporting the provision of care to underserved and vulnerable populations.

VACCINE HESITANCY¹⁴⁵

One of the top 10 global health threats according to the WHO, vaccine hesitancy refers to the reluctance or refusal of people to vaccinate despite availability of vaccination services. Vaccine hesitancy has been reported in more than 90 percent of countries in the world and is being fueled by a number of factors, including the spread of misinformation and disinformation about vaccine safety; complacency; inconvenience and inaccessibility; and lack of confidence. The rise of vaccine hesitancy threatens to reverse the tremendous global progress made in preventing vaccine-preventable diseases. For example, immunization for measles, a vaccine-preventable disease that was largely eliminated following widespread use of the measles-mumps-rubella (MMR) vaccine, has now decreased below the threshold set by the WHO as that required for herd immunity.

WORLD HEALTH ORGANIZATION CONTINGENCY FUND FOR EMERGENCIES (CFE)¹⁴⁶

Set up as part of a series of WHO institutional reforms in the wake of the scathing criticism it received for its late response to the 2014-2016 Ebola crisis in West Africa, the CFE gives the WHO the resources to respond immediately to disease outbreaks and humanitarian crises with health consequences. The ability to respond quickly—in as little as 24 hours—before other funding is mobilized can stop a health emergency from spiraling out of control, saving lives and resources. As of March 2019, 16 countries, led by Germany, Japan, and the United Kingdom, had contributed \$70 million to support the CFE.

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governments may have little presence, but these flexibilities pertain only to the small number of low- and middle-income countries still eligible for Gavi support. With a Geneva-based secretariat and no staff at the country level, Gavi is limited in its ability to provide on-the-ground support during an outbreak. The United States could also urge the WHO's CEF to set aside monies to prevent, rather than just respond to, emergencies, but the United States has not yet contributed to the Fund so may have limited influence.

86. Expert estimate of the cost of training for 150 trainees is based on estimated average cost of \$6,500 per trainee for FETP-Frontline 3-month training for local public health staff. As the GPEI experience has made clear, among the greatest challenges with delivering vaccines in disordered settings is enabling trained personnel to quickly and safely access target populations and to deliver vaccines without threat of violence. The GPEI has catalogued a set of practices enabling vaccinators to collaborate with local security forces to negotiate cease fires and deliver vaccines.

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EXHIBIT 466

**Statement from the Global Preparedness Monitoring Board on the
Outbreak of 2019-novel Coronavirus (2019-nCoV)**

30 January 2020, Geneva – The Global Preparedness Monitoring Board (GPMB) convened on **27 January 2020** to discuss the current outbreak of 2019-nCoV which was first detected in Wuhan, China and is now quickly spreading internationally. The Board commends the speed of the response so far by countries and the World Health Organization (WHO), the transparency of China in sharing information and the genome sequence of the virus, and the strong collaboration between China and affected countries and with WHO. The Board however is concerned that many countries remain unprepared and urges leaders in all countries to take immediate action to ensure that they have the necessary capacities in place.

The Board recommends the following urgent actions:

- 1) Countries, institutions, communities and partners must ensure that all relevant information about the outbreak is shared openly and rapidly, to support the response in accordance with the International Health Regulations (IHR (2005));
- 2) All countries and local governments, including those that have not yet been affected, must urgently dedicate resources to building their essential preparedness capacities (as described in the IHR (2005) to prevent, detect, inform about and respond to the outbreak, to strengthen their health systems, and are urged to follow WHO technical guidance for control measures, in line with the IHR(2005));
- 3) The research and development community, including national research institutions and related dedicated efforts in the public and private sectors, must urgently accelerate the coordinated development of vaccines, diagnostics and therapeutics against the coronavirus. The private sector and initiatives as the Coalition for Epidemic Preparedness Innovations (CEPI) should use the vaccine research they are supporting for other coronaviruses, such as MERS-CoV, for exploring the development of vaccines against 2019-nCoV. Prompt and unrestricted sharing of coronavirus specimens and clinical samples is essential to advancing this research and development, early detection and the global public health response. To ensure rapid access to emerging findings, all peer-reviewed research publications relevant to the outbreak should be made open access immediately, and research findings relevant to the outbreak should be shared rapidly with WHO. Countries and the international community should expand understanding of potential trajectories of the epidemic and its social-economic impact;
- 4) Countries must support and enable WHO's central role in the response, including by fully and sustainably financing WHO's preparedness and response activities through voluntary contributions and replenishment of the WHO Contingency Fund for Emergencies, and to strengthen WHO's communication capacity. WHO should lead the global response through effective action to minimize risks of transmission, support care for people who are infected, share critical risk and event information, counter misinformation, engage with governments to support their preparedness and response efforts, and facilitate expert epidemiologic and other technical assistance to countries;

5) All donors, including governments, the World Bank, Regional Development Banks, the GFATM, and Gavi should financially support lower resourced countries, inclusive of using the Pandemic Emergency Facility and other existing channels. Donors and development partners should prioritize financial and technical support to low- and middle-income countries/communities at-risk to assist them in building these capacities, notably to improve early detection and control of the virus, limit the risk of transmission, and their ability to respond. Collaboration should be strengthened across national and sub-national public health agencies, and across the public and private sectors to ensure availability of testing and supplies of personal protective equipment;

6) Ensuring that national and international communities are properly informed and trust the response is crucial to controlling the outbreak. Countries, institutions, the media and WHO should regularly and proactively communicate factual information about the outbreak, how to prepare for and prevent infection, in a transparent, timely, accurate and open manner, and should find ways to mobilize and engage local organizations and communities in all stages of planning and implementation of response activities.

About the GPMB

As an independent monitoring and advocacy body, the [GPMB](#) urges political action to prepare for and mitigate the effects of global health emergencies. Co-convened by the World Bank Group and the WHO, the GPMB works independently to provide expert assessments and recommendations on the state of global preparedness. The opinions and recommendations of the GPMB are those of the Board and do not necessarily represent the views of the World Bank Group and WHO.

The GPMB *A World At Risk* annual report: http://apps.who.int/gpmb/annual_report.html

EXHIBIT 467

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[1](https://thenewsteader.com/2020/01/30/statement-from-the-global-preparedness-monitoring-board-on-the-outbreak-of-2019-novel-coronavirus-2019-ncov) (<https://thenewsteader.com/2020/01/30/statement-from-the-global-preparedness-monitoring-board-on-the-outbreak-of-2019-novel-coronavirus-2019-ncov>)**Exhibit 467**

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- 2) All countries and local governments, including those that have not yet been affected, must urgently dedicate resources to building their essential preparedness capacities (as described in the IHR (2005) to prevent, detect, inform about and respond to the outbreak, to strengthen their health systems, and are urged to follow WHO technical guidance for control measures, in line with the IHR(2005);
- 3) The research and development community, including national research institutions and related dedicated efforts in the public and private sectors, must urgently accelerate the coordinated development of vaccines, diagnostics and therapeutics against the coronavirus. The private sector and initiatives as the Coalition for Epidemic Preparedness Innovations (CEPI) should use the vaccine research they are supporting for other coronaviruses, such as MERS-CoV, for exploring the development of vaccines against 2019-nCoV. Prompt and unrestricted sharing of coronavirus specimens and clinical samples is essential to advancing this research and development, early detection and the global public health response. To ensure rapid access to emerging findings, all peer-reviewed research publications relevant to the outbreak should be made open access immediately, and research findings relevant to the outbreak should be shared rapidly with WHO. Countries and the international community should expand understanding of potential trajectories of the epidemic and its social-economic impact;
- 4) Countries must support and enable WHO's central role in the response, including by fully and sustainably (sic) financing WHO's preparedness and response activities through voluntary contributions and replenishment of the WHO Contingency Fund for Emergencies, and to strengthen WHO's communication capacity. WHO should lead the global response through effective action to minimize risks of transmission, support care for people who are infected, share critical risk and event information, counter misinformation, engage with governments to support their preparedness and response efforts, and facilitate expert epidemiologic and other technical assistance to countries;
- 5) All donors, including governments, the World Bank, Regional Development Banks, the GFATM, and Gavi should financially support lower resourced countries, inclusive of using the Pandemic Emergency Facility and other existing channels. Donors and development partners should prioritize financial and technical support to low- and middle-income countries/communities at-risk to assist them in building these capacities, notably to improve early detection and control of the virus, limit the risk of transmission, and their ability to respond. Collaboration should be strengthened across national and sub-national public health agencies, and across the public and private sectors to ensure availability of testing and supplies of personal protective equipment;
- 6) Ensuring that national and international communities are properly informed and trust the response is crucial to controlling the outbreak. Countries, institutions, the media and WHO should regularly and proactively communicate factual information about the outbreak, how to prepare for and prevent infection, in a transparent, timely, accurate and open manner, and should find ways to mobilize and engage local organizations and communities in all stages of planning and implementation of response activities.

About the GPMB

As an independent monitoring and advocacy body, the GPMB urges political action to prepare for and mitigate the effects of global health emergencies. Co-convened by the World Bank Group and the WHO, the GPMB works independently to provide expert assessments and recommendations on the state of global preparedness. The opinions and recommendations of the GPMB are those of the Board and do not necessarily represent the views of the World Bank Group and WHO.

The GPMB A World At Risk annual report: http://apps.who.int/gpmb/annual_report.html (http://apps.who.int/gpmb/annual_report.html).

EXHIBIT 468

The Global Preparedness Monitoring Board calls for a Scaled-Up Global Response to COVID-19: Estimated Costs and Funding Sources

Executive Summary

The rapid spread of COVID-19 has already had profound health, social and economic impact around the world. As the true scale of infection becomes apparent, disruption to people, communities, businesses, health systems and economies will continue to grow - international financial institutions and the major economic nations must respond decisively and immediately to the global response at a scale commensurate to the size of the problem. **This is why the Global Preparedness Monitoring Board (GPMB) is calling for the immediate injection of at least \$8bn of new funding.**

The GPMB warmly welcomes the announcement from the World Bank on **03/03/2020** to commit up to \$12bn of support for the COVID-19 country response, which will help strengthen the preparedness and response capacities of countries with the weakest health systems. The IMF's \$50bn coronavirus package announced on 03/04/2020 will be key to supporting economies. But there remain significant urgent gaps that this money does not address.

Key needs include: ■ fully funding the WHO to coordinate and prioritize support efforts to the most vulnerable countries ■ developing new diagnostics, therapeutics, and vaccines ■ strengthening unmet needs for regional surveillance and coordination ■ ensuring sufficient supplies of protective equipment for health workers.

The costs of inaction, or responding slowly, are significant both in human and economic terms. Investing now will significantly reduce these costs. Dr Tedros Adhanom Ghebreyesus, WHO Director General has been clear on the urgency, stating that "**We are at a decisive point...If you act aggressively now, you can contain this virus**".

Multilateral financial institutions and G7 and G20 governments should provide immediate funding to meet these needs.

The challenge the world is facing in health

Health – it is only a matter of time before COVID-19 reaches countries with much weaker health systems than China, South Korea, the US or Europe. When it does, the case fatality rate may increase due to lack of access to critical care facilities for the most severe cases. We already have the first cases on the African continent. Even in countries with strong healthcare systems, the pressure on emergency room services and laboratories will cause huge challenges.

- COVID-19 is highly transmissible (someone with COVID-19 will, on average, infect two to three other people) and has a case fatality rate higher than that of seasonal influenza.
- COVID-19 has spread rapidly with around 90,000 confirmed cases in 73 countries, and 3,112 deaths (as of 03/03/20). It is highly likely these figures are substantial underestimates (perhaps up to 20 times lower) due to the challenges of identifying and recording cases.
- COVID-19 has put strain on already stretched health systems and infecting large numbers of health workers.
- The number of cases and deaths has already significantly exceeded those of the 2003 SARS outbreak - there have been 10 times the number of cases in one quarter of the time.
- A range of future scenarios is possible but the prospect of a pandemic with multiple waves is increasing.

The wider impact of COVID-19 – lives and livelihoods

COVID-19 is now a whole of society issue impacting many aspects of society and reaching across industries.

Social – COVID-19 has brought significant disruption to societies around the world. Businesses and schools have closed, large public gatherings been cancelled, cities and towns placed in lockdown, and travel restricted. Fear is taking hold – fake news is gathering ground.

Economic – the growth of cases reported around the world led to a stock market plunge last week, with around \$6tn knocked off global share prices. The outbreak is on course to knock 1.3% off global GDP. On its current trajectory, China is expected to lose up to \$62bn in the first quarter of 2020 with global losses estimated to be \$280bn within the same period. Such losses would be greater than the economic losses from SARS (2003), Ebola (2014-2016), MERS in South Korea (2015), and Zika (2015-2016) *combined*. While it is desirable to end public health measures as early as possible to ease the social and economic disruptions, that increases the risk of recurrences.

Supply chains – China, as well as other affected areas such as northern Italy, manufactures essential goods for many industries. Of particular concern for this outbreak, China is the supplier of active pharmaceutical ingredients for many medicines – a significant disruption to production could substantially impact supplies of antibiotics and other critical drugs. There are many similar examples across sectors and across countries.

What international financial institutions and major economic nations must do

We cannot wait to take action given the unprecedented speed at which this epidemic is progressing. A massive global response is required, one that assumes a worst-case scenario. This is a problem that has already gone far beyond the public health sphere. The international financial institutions and the major economic nations should act as if we are facing a global pandemic with an impact which may reach 1918 influenza proportions.

The Global Preparedness Monitoring Board (GPMB) estimates that a minimum of \$8bn of new funding is required immediately to address the most urgent threats posed by COVID-19 - mobilizing these financial resources should be an urgent priority requiring bold leadership from G7, G20 and Multilateral Financial Institutions now.

The GPMB calculates that the most critical funding gaps which need to be addressed are:

Activity	Estimated cost (\$bn)
Support for emergency response via the WHO	1
Strengthening unmet needs for regional surveillance and control efforts for COVID-19	0.25
Development of COVID-19 vaccines	2.0
Distributed manufacturing and delivery of COVID-19 vaccines	1.0
Development of therapeutics to treat COVID-19	1.5
Development of diagnostics for COVID-19	0.5
Manufacturing and delivery of COVID-19 therapeutics and diagnostics	1.0
Stockpiling of COVID-19 vaccines and PPE (single replenishment cycle)	0.75
Total	8

Section1: The challenge the world is facing in health

COVID-19, is highly transmissible. Someone with COVID-19 will, on average, infect two to three other people. Infected people who are asymptomatic or have just mild symptoms can transmit the disease. The case fatality rate is higher than that of seasonal influenza. The largest study conducted to date, which included 72,314 confirmed cases of COVID-19, found that the overall case fatality rate was 2.3%. This is close to that of the 1918 Spanish Flu which may have killed close to 50 million people.

No specific treatment or vaccine is available. Research efforts have started on both therapeutics and vaccines, but this has to be done at a speed and at a scale that is unprecedented, from research through development to manufacturing that can meet the global demand in an accessible and equitable way. Multiple candidates need to be developed in parallel at scale and at risk – there is not the time to do in sequence.

New cases outside mainland China now exceed the number inside and all G7 nations have confirmed cases.

There is an increasing likelihood of a pandemic. In the Republic of Korea, Italy, and Iran, the number of reported infections more than doubled in just two days. There are also concerns that Southeast Asian countries including Myanmar, Laos, Brunei, East Timor, and Indonesia may be undergoing "[a silent epidemic](#)."

As of 3 March 2020, the WHO reports more than 90,000 confirmed cases in 73 countries, and 3,112 deaths. It is highly likely these figures are substantial underestimates due to the challenges of identifying and recording cases. In comparison, there were [774 reported deaths](#) from the 2003 SARS outbreak; there have been 10 times the number of cases of COVID-19 in one quarter of the time.

COVID-19 is placing huge demands on health systems. At the start of the outbreak, Hubei Province, the center of China's outbreak, had less than 2000 hospital beds to treat patients with infectious diseases. Two new hospitals with more than 2000 beds were built within two weeks to treat critically ill patients with COVID-19 and 11 gymnasiums or exhibition centers were turned into makeshift COVID-19 hospitals with over 10 000 beds. Italy, Republic of Korea, and Japan have also taken extraordinary measures to increase the capacity for treating patients.

Hospitalized patients have a high risk of needing intensive care. Overall, in the study cited above, 3,110 people out of the 72,314 infected people (4.3%) required critical care. However, once hospitalized, the risk of needing such care is much higher. Hospitalized patients in Wuhan have had a high rate of transfer to the intensive care unit: a study by Wang and colleagues of 138 hospitalized patients found that 36 patients (26.1%) were transferred to the intensive care unit because of complications.

A large number of health workers are infected, placing strain on already stretched health systems. China's National Health Commission reports (in a Chinese language [publication](#)) that 1,716 health workers have been infected (87.3% of these cases are in Hubei) and six have died. This strain on health systems also interrupts the care of people with other diseases. For example, over 30,000 doctors and nurses from other regions of China have been sent to Hubei —leaving shortages of health professionals elsewhere. Countries like Italy are also experiencing a great amount of pressure on the health system with reports of insufficient intensive care capacity to accommodate all the individuals severely affected by COVID-19. The WHO estimates that about 89 million medical masks, 76 million examination gloves and 1.6 million goggles will be required globally for health care workers.

A range of future scenarios is possible but the likelihood of a pandemic with multiple waves of COVID-19 is increasing. The costs of inaction, or responding slowly, are huge both in human and economic terms. Investing now will save lives and significantly reduce economic costs.

Social – COVID-19 has brought significant disruption to society. Businesses have closed, large public gatherings been cancelled, cities placed in lockdown, and travel restricted. These public health measures have materially impacted lives and livelihoods. Fear is increasing. Access to trusted information has also been challenging for some communities and there are organized disinformation campaigns.

Economic – COVID-19 is fast becoming an “economic pandemic.” Four of the world’s top economies, China, Japan, Korea and Italy— representing about 27% of global GDP—are now battling to contain transmission and the lifting of public health measures too early could cause recurrences and further disruption. This epidemic is impacting all G7 and G20 nations but will disproportionately affect vulnerable people in low- and middle-income countries.

The reporting of more cases outside of China **led to a stock market plunge last week, with the biggest weekly losses since the 2008 financial crash** and around \$6tn knocked off global share prices. If the coronavirus becomes a pandemic, it could cost the global economy more than [\\$1tn in lost output, or 1.3%](#) of global GDP. Another recent report suggests the hit to global GDP could be far larger at between 2.3 – 9.2 trillion USD. If the outbreak continues on its current trajectory, China is expected to lose up to \$62bn in the first quarter of 2020 with global losses estimated to be \$280bn within the same period. [South Korea recently injected more than \\$13bn](#) in emergency funds to stoke economic activity. The [OECD](#) has cut Europe’s GDP estimate by 0.3% while Italy, the country most affected in Europe so far, is expected to lose 0.4% of its GDP. Sectors such as tourism are expected to take a big hit in Italy, with an expected cancellation of over 22 million reservations and an economic loss of Euro 2.77bn. Such global losses would be greater than the economic losses from SARS (2003), Ebola (2014-2016), MERS in South Korea (2015), and Zika (2015-2016) *combined*.

Supply Chains – China, as well as other affected areas such as northern Italy, manufactures essential goods for many industries and has [more than doubled its share of trade with the rest of the world](#) since the 2003 SARS epidemic. Of particular concern for this outbreak are the impacts from a health perspective. China is the main supplier of active pharmaceutical ingredients for the world’s antibiotics’ manufacturers – a significant disruption to production could substantially impact supplies of these critical drugs. There are many similar examples across sectors, including in automobile production and mobile phone manufacturing, with supply chain issues emerging in northern Italy and many other countries. Given the extent of disruption of the workforce in those countries affected already, the impacts of this in the coming months could be significant.

Return on investment. Proactive action now can alter the course of this epidemic and mitigate its global impact. World Bank estimates strengthened health systems that avoid the damages associated with pandemics would result in global public benefit of over [\\$30bn a year](#). Recently, we have seen the benefits of investing in preparedness in the context of weak health systems, such as the [effective responses to Ebola in Nigeria and Uganda](#).

Section 3: What international financial institutions and major economic nations must do

World leaders and international financial institutions cannot wait to take action given the unprecedented speed at which this epidemic is progressing. A massive global response should be mounted, one that assumes a worst-case scenario. This is a problem that has already gone far beyond just the health sphere and needs the support of heads of state, finance ministers and other economic actors to solve it. Private-public cooperation will be crucial and should harness the appetite from companies to support the COVID-19 response, including groups being coordinated by World Economic Forum. The global response must be commensurate to the enormous human, social, and economic toll that COVID-19 has already inflicted, and the possibility of far more suffering.

The GPMB estimate that a minimum of \$8bn of new funding is required immediately to address the most urgent threats posed by COVID-19 - mobilising these financial resources should be an urgent priority for G7, G20 and the Multilateral Financial Institutions.

In order to ensure a comprehensive set of actions they must:

1. *Strengthen the preparedness and response capacities of those countries with the weakest health systems*

Resource-constrained countries that are already tackling an outbreak need support to bolster their treatment and containment efforts. The most acute need in many countries is to strengthen clinical services, including in-patient and intensive care, urgently closing gaps in medical supplies (e.g. oxygen), protective equipment for healthcare workers, and diagnostics. Low- and middle-income countries need urgent help to strengthen their pandemic preparedness capabilities, including national surveillance and screening systems.

2. *Fully provide the financial means to enable the WHO to coordinate worldwide efforts and prioritize support to the most vulnerable countries*

The WHO's Strategic Preparedness and Response Plan coordinates the global response and supports national preparedness and response for COVID-19, helping countries to develop national operational plans and scale-up country readiness and response operations.

3. *Develop new diagnostics, therapeutics and vaccines to treat COVID-19 and build surge capacity to manufacture them*

Efforts to develop COVID-19 vaccines, therapeutics, and diagnostics must be accelerated. Once these are developed, we must also ensure that they are available to all at an affordable price. There are other [research priorities](#) for controlling the epidemic including how to optimize standard of care, the use of protective equipment and understanding animal hosts and virus transmissibility.

4. *Strengthen regional surveillance and coordination*

In the wake of other outbreaks such as Ebola in West Africa, a number of initiatives were launched to coordinate regional pandemic preparedness efforts, including regional surveillance. Two examples are the Africa CDC and the Indo-Pacific Health Security Initiative. These types of activities should be fully supported.

5. *Ensure sufficient supplies of protective equipment for health workers*

Funding of \$8bn could make a substantial difference in tackling this global epidemic. About half of this could fund the development, deployment, and stockpiling of critically needed technologies, including new vaccines. This

investment is dwarfed by the \$280bn of costs that COVID-19 is already on course to cause in the first quarter of 2020. It would help prevent even greater losses than this.

The immediate need is to prevent further illness, deaths, and social and economic devastation from the current COVID-19 outbreak. Over the longer term, these investments would also help to put in place a pandemic response system that is “fit for purpose” in handling the inevitable outbreaks of the future.

Section 4: Costings

In order to establish these five priorities, an approximate “price tag” was derived from using a combination of existing estimates of the costs and professional judgement. A reasonable conservative estimate is approximately \$8bn. A breakdown is given below:

- **Fully fund the WHO to support preparedness and emergency response: \$1bn.** WHO’s emergency appeal for the COVID-19 response [requests](#) \$61.5m for the period February to April 2020. This figure is included in WHO’s Strategic Preparedness and Response Plan, which calls for a total resource requirement of \$675m. Full replenishment of the [Contingency Fund for Emergencies](#), which has a capitalization target of \$100 million and needs to be replenished with around \$25-50 million annually depending on the number and extent of outbreaks, would be \$100 million. Finally, \$225 million is needed to close the [annual shortfall](#) facing the WHO’s Health Systems Preparedness Programmes.
- **Strengthen unmet needs for regional surveillance and control efforts: \$250m.** The World Bank previously [funded](#) the Africa CDC, along with the Federal Republic of Ethiopia and the Republic of Zambia to “strengthen continental and regional response systems to combat epidemics and advance critical public health priorities.” Replenishment at the same level of funding would be reasonable in the wake of COVID-19.
- **Development of COVID-19 vaccines: \$2bn.** CEPI estimates that it needs up to \$2bn to accelerate vaccine development.¹ This estimate presumes development to the point at which the vaccines can be licensed or used under emergency use provisions—the figure *does not include* costs for subsequent manufacturing, delivery or administration.
- **Distributed manufacturing and delivery of COVID-19 vaccines: \$1bn.** A highly conservative estimate is that manufacturing and delivery to Gavi-eligible countries would be at least \$1bn.
- **Development of therapeutics to treat COVID-19: \$1.5bn.** This estimate is based on a portfolio modeling tool, the [Portfolio-to-Impact \(P2I\) tool](#), developed by TDR and CIGH. It would cost about \$1.5bn to develop one simple new chemical entity (NCE), one complex NCE, one simple repurposed drug, and one complex repurposed drug, and one biologic (monoclonal antibody product).
- **Development of diagnostics for COVID-19: \$0.5bn.** This estimate assumes [development costs](#) to develop a suite of diagnostics—including diagnostic assays and simple technical platforms.
- **Manufacturing and delivery of COVID-19 therapeutics and diagnostics: \$1bn.** A highly conservative estimate is that manufacturing and support for delivery in LMICs would be at least \$1bn.
- **Stockpile of COVID-19 vaccines and PPE: \$0.75bn** (single replenishment cycle) Previous [estimates](#) suggested that stockpiling of an H5N1 vaccine would cost about \$360m per replenishment cycle.

An investment of \$8bn now is small compared to the costs of inaction.

Acknowledgements: The GPMB would like to thank Professor Gavin Yamey at Duke University for his support and expertise on this piece of work.

¹ CEPI paper, February 14 2020, “Investment Case: Rapid Vaccine Development for COVID-19.”

EXHIBIT 469

Statement on the COVID-19 pandemic and the Extraordinary G20 Leaders' Summit on COVID-19

Geneva, 1 April 2020 - The Global Preparedness Monitoring Board (GPMB) met on 30 March 2020 to discuss the COVID-19 pandemic, and the commitments made by world leaders during the Extraordinary G20 Leaders' Summit on COVID-19 held on 26 March 2020.

The GPMB welcomes the initiative taken by G20 Leaders and their statement on COVID-19, particularly their commitment to fill existing financial gaps in the response.

The Board will monitor the implementation of the commitments made by G20 leaders to ensure progress is made and will continue to advocate at the highest levels to draw attention to the most urgent preparedness gaps.

The Board is pleased to see the commitment of G20 leaders to develop a concrete and collective plan of action that places the health and wellbeing of people and communities at the center, but recognizes that there is still an urgent need for more collective action. On 9 March the GPMB called for G7 and G20 leaders to immediately inject US\$ 8 billion of new funding to bolster action at the global level in the response to COVID-19. While some countries have made significant contributions since then, the world is still far short of this immediate funding need and it is important that others step up urgently. The Board hopes that the strong commitments made during the G20 Extraordinary Summit will lead to equally strong action by leaders.

The Board also welcomes the request by G20 to WHO in cooperation with relevant organizations, to assess gaps in pandemic preparedness with the view to establish a global initiative on pandemic preparedness and response.

COVID-19 is a global crisis, impacting all sectors, industries, and people, without regard to borders. The Board strongly believes that successfully stopping this pandemic will require countries to work together, with the international community, the private sector, and communities, to ensure coherent action and a comprehensive approach that not only addresses immediate health needs, but also the socio-economic impact the pandemic will have on all people, notably vulnerable countries and communities. G20 leaders should ensure that global public goods, such as R&D for vaccines, therapeutics and diagnostics for COVID-19, are funded and that mechanisms are put in place to ensure equitable and affordable access by all.

The pandemic has the potential to jeopardize progress made over decades to fight other diseases such HIV, polio and malaria and to impact delivery of health care everywhere. Leaders must continue to invest in strengthening health systems and infrastructure to ensure that other health needs are met during the pandemic. As billions of people are now physically distancing and many are isolated and have lost employment, leaders should also ensure that the mental health needs and the psychosocial dimensions of the pandemic are addressed.

As the Board highlighted in its 2019 annual report, *A World at Risk*, significant gaps persist that urgently need to be addressed to stop the COVID-19 crisis and mitigate its impact, but also to prevent future epidemics and pandemics. The GPMB stands ready to support WHO in assessing and monitoring these gaps.

About the GPMB

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The GPMB annual report, *A World At Risk*, can be found here:

http://apps.who.int/gpmb/annual_report.html

EXHIBIT 470

GPMB Statement on the launch of the Access to COVID-19 Tools (ACT) Accelerator

24 April 2020

The Global Preparedness Monitoring Board (GPMB) warmly welcomes today's launch of the Access to COVID-19 Tools (ACT) Accelerator, a global collaboration mechanism to accelerate development, production and deployment of safe and effective technologies to prevent, diagnose and treat COVID-19.

This initiative of WHO, the United Nations, heads of state and government, international and regional organizations, research organizations, manufacturers and funders, has the potential to transform the pandemic response, making new vaccines, treatments and diagnostic tests rapidly accessible to everyone, everywhere.

Earlier this year, the **GPMB highlighted this critical need and called for the immediate injection of at least USD 8 billion** of new funding to support the development and production of new vaccines, drugs and diagnostics, and strengthen the global response to COVID-19.

We call on all partners to immediately fill the funding gaps in the COVID-19 response, and we welcome the initiative of the European Union in collaboration with global partners to kick-start a pledging effort – the Coronavirus Global Response - starting on 4 May 2020. We commend UN Member States for their commitment to 'international cooperation to ensure global access to medicines, vaccines and medical equipment to face COVID-19'.

Dr Gro Harlem Brundtland, former Prime Minister of Norway, former Director-General of WHO and co-chair of the GPMB said, *"A global pandemic requires a global response. The world is coming together to overcome a common enemy, by our collective actions we will defeat it."*

Mr Elhadj As Sy, chair of the Kofi Annan Foundation, former Secretary-General of the International Federation of Red Cross and Red Crescent Societies, and co-chair of the GPMB said, *"As with other health crises, COVID-19 is exposing existing inequalities and exacerbating vulnerabilities globally. To stop this pandemic, we must ensure that no one is left behind."*

The GPMB calls on all stakeholders in this extraordinary effort to work together to ensure that the vaccines, treatments, diagnostic tests and other technologies developed through this unprecedented collaboration are accessible to all, affordable, and allocated in such a way as to have maximum impact on stopping the pandemic and protecting the vulnerable.

Now is the time for solidarity and unity. Now is the time for collective action, collective resourcing and collective accountability.

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The GPMB 'A World At Risk' annual report: http://apps.who.int/gpmb/annual_report.html. For further details contact gpmbsecretariat@who.int